Australian Government

Australian Pesticides and Veterinary Medicines Authority

Submission to the Productivity Commission study into chemicals and plastics regulation

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Abbreviations and acronyms

AATSE	Australian Academy of Technological Sciences and Engineering
AERP	Adverse Experience Reporting Program
agvet	agricultural and veterinary
Agvet Code	*Agricultural and Veterinary Chemicals Code Act 1994*
Agvet Code Regulations	*Agricultural and Veterinary Chemicals Code Regulations 1995*
AHMAC	Australian Health Ministers Advisory Council
ANAO	Australian National Audit Office
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
ARMCANZ	Agriculture and Resource Management Council of Australia and new Zealand
CCC	Community Consultative Committee
COAG	Council of Governments
CODEX	Codex Alimentarius Commission
CRIS	Cost Recovery Impact Statement
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DAFF	Department of Agriculture, Fisheries and Forestry
DEW	Department of Environment and Water Resources
DOHA	Department of Health and Ageing
EARS	Electronic Application and Registration System
EPHC	Environment Protection and Heritage Council
FAO	Food and Agriculture Organisation
FRSC	Food Regulation Standing Committee
FSANZ	Food Standards Australia and New Zealand
GHS	Globally Harmonised System for Labelling
ILC	Industry Liaison Committee
ISO	International Organisation for Standardisation
ITC	Industry Technical Committee
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint Meeting on Pesticides Residues
MLS ILC	Manufacturers Licensing Scheme Industry Liaison Committee
MORAG	Manual of Requirements and Guidelines
MOU	Memorandum of Understanding
MRL	Maximum Residue Limit

NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NRS	National Registration Scheme
NZFSA	New Zealand Food Safety Authority
OCS	Office of Chemical Safety
OECD	Organisation for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator
OH&S	Occupational Health and Safety
PIMC	Primary Industries Ministerial Council
PISC	Primary Industries Standing Committee
PMRA	Canadian Pest Management Regulatory Agency
PSD	United Kingdom Pesticides Safety Directorate
PSIC	Product Safety and Integrity Committee
RLC	Registration Liaison Committee
SWG	Signatories Working Group
TGA	Therapeutic Goods Administration
USFDA	United States Food and Drug Administration
VDD	Canadian Veterinary Drugs Directorate
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products
VMD	United Kingdom Veterinary Medicines Directorate
WHO	World Health Organisation

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Executive summary

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government Statutory Authority responsible for regulating the supply of agricultural and veterinary (agvet) chemicals to the Australian marketplace. The APVMA also administers the National Registration Scheme (NRS), which sets out the regulatory framework for the management of agvet chemicals in Australia. The APVMA works in partnership with state and territory governments and with the active involvement of other Australian Government departments and agencies.

The NRS was established to protect people, plants, animals and the environment from unintentional or undue harm by ensuring that agvet chemical products are safe, effective, and that their use does not unduly impact on Australia's trade. The APVMA is responsible for the regulation of agvet chemicals up to and including the point of retail sale. The state and territory governments are responsible for regulating the use of agvet chemicals once they are sold.

Previous reviews on the regulation of agvet chemicals have examined existing regulatory arrangements and the ongoing challenges of the regulatory environment. These reviews have highlighted the need for ongoing reform and continuous improvement to standardise and achieve efficiencies in the delivery of regulatory objectives.

This submission sets out the key findings of previous reviews relevant to the Productivity Commission's study into chemicals and plastics regulation. It also outlines the current reform agenda for agvet chemical regulation, in both the operational and policy arena. Key reform activities expected to have a positive effect on the productivity of the chemical and primary industries are presented.

From its analysis of prior reviews, current regulatory arrangements and NRS objectives, the APVMA has identified three areas of opportunity for improvement. The APVMA recommends six proposals which, we believe, will improve the efficiency and effectiveness of agvet chemical regulation in Australia.

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1 Introduction

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an Australian Government Statutory Authority within the portfolio of the Department of Agriculture, Fisheries and Forestry (DAFF). It regulates the supply of agricultural and veterinary (agvet) chemicals in the Australian marketplace up to and including the point of retail sale. Each Australian state and territory then regulates the use of agvet chemicals in its respective jurisdiction. This arrangement is the National Registration Scheme (NRS), which was established in September 1995 by inter-governmental agreement of agriculture ministers from Australian, state and territory governments. The NRS was established in this way because of constitutional limitations on the Commonwealth's ability to legislate over agvet chemicals. The regulatory framework is a complementary one with a shared division of responsibilities between the Commonwealth and the states and territories.

The current system of agvet chemical regulation was implemented following a 1990 Senate Select Committee inquiry into agvet chemicals, *Report of the Senate Select Committee on Agricultural and Veterinary Chemicals in Australia*[1]. This inquiry was triggered by the 1987 detection of exceptionally high organochlorine residues in Australian export beef. Prior to the 1990s the supply and use of agvet chemicals was regulated by state legislation. The single national scheme, the NRS, was created to streamline registration and review processes and promote national consistency.

The APVMA's mission is to protect the health and safety of people, animals and crops, the environment, and trade and support Australian primary industries through evidence-based effective and efficient regulation of agvet chemicals. It does this through the evaluation and registration of agvet chemical products, issuing permits, reviewing existing chemicals and ensuring their compliance with standards during manufacture and in the market.

1.1 Australian situation

The Australian agvet chemical market is relatively small on a world scale. The Australian market comprises less than two per cent of the global distribution of agvet chemicals. Even so, the regulatory system delivers outcomes comparable to those of other first world nations in terms of safety to consumers and the environment. The system is respected internationally and underpins

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1 Commonwealth of Australia, *Report of the Senate Select Committee on Agricultural and Veterinary Chemicals*, Australian Senate Publication Unit, Canberra, 1991.

Australia’s export trade in agricultural commodities. This is an important aspect as Australia exports around two-thirds (65 per cent) of the agricultural commodities it produces. In 2004–05 agricultural products accounted for one-fifth of Australian merchandise exports.

2 Objectives of the current agvet chemical risk management scheme

NRS policy objectives are set out in the APVMA's governing legislation and are reflected in the APVMA's Mission Statement and its Corporate Plan[2]. The NRS was established to protect people, plants, animals and the environment from unintentional or undue harm by ensuring that the use of chemical products is safe, effective, and will not unduly impact on Australia's trade. The scheme aims to support primary industry by recognising the importance of these factors and the role of agvet chemicals in underpinning the productivity of the primary sector.

Agvet chemicals will continue to play a vital role in Australia's production of high quality food by providing efficient and effective pest and disease control. In Australia and internationally there is a heightened awareness of the potential environmental and public health risks associated with chemical use and there is strong pressure from community groups for governments to assure the protection and safety of people and the environment. Regulatory systems must balance the agricultural production needs for access to chemicals, including new chemical technology, with the expectations and needs of the wider community.

The APVMA operates in a complex regulatory environment. This is best illustrated by the diversity of its stakeholders who include:

- the chemical industry;
- farmers and farm workers;
- the general community;
- Australian state and territory governments;
- users of agvet chemicals; and
- other national and international regulators.

To understand and consult with these diverse groups, the APVMA operates a number of consultative and liaison committees, including the Community Consultative Committee (CCC), the Industry Liaison Committee (ILC), the Industry Technical Committee (ITC), the Manufacturers Licensing

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[2] The APVMA Corporate Plan is available from the APVMA website at http://www.apvma.gov.au/publications/downloads/CorporatePlan06.pdf.

Scheme Industry Liaison Committee (MLS ILC) and the Registration Liaison Committee (RLC)[3]. In addition to these consultative structures the APVMA routinely conducts consultations with its stakeholders, seeks their input on issues, decisions and scientific assessment outcomes relating to registration activities[4] and the review of existing chemicals, as well as on proposals to reform requirements or procedures.

The APVMA notes that a key theme of the Commission's study is to determine how effective regulations are at delivering policy objectives. One objective measure of the effectiveness of agvet chemical regulation is data collected through the National Residues Survey. This survey provides data on compliance with label instructions and is an assessment tool for monitoring the food safety outcomes of regulation (acceptable residues in food). The APVMA also operates an Adverse Experience Reporting Program (AERP) to monitor any unintended effects from the use of chemical products registered by the APVMA. This reporting program provides in-use information and is also an indication of the effectiveness of the chemicals assessment and regulation framework[5]. Furthermore, the lack of significant public health, environment or trade incidents in recent years related to chemical use, such as the 1987 detection of exceptionally high organochlorine residues in Australian export beef, is to an extent a measure of the effectiveness of agvet chemical regulation.

The development of an appropriate performance management framework is important to evaluate the effectiveness of agvet chemical policy and to underpin public confidence in the agvet chemical regulation system. In recognition of this the Product Safety and Integrity Committee (PSIC), a sub-committee of the Primary Industries Ministerial Council (PIMC), has developed a framework of regulatory outcomes against which performance may be measured. The framework encompasses a range of benchmarking tools including residue testing, reporting of adverse experiences and other impacts.

Reliable performance measures and indicators are important tools for governments to effectively determine whether regulatory frameworks are appropriately delivering stated policy objectives. It is only through consideration of such information that the most appropriate regulatory balance and regulatory burden can be determined to achieve the policy objectives in an efficient and equitable manner. Reliable objective measures of effectiveness facilitate more holistic consideration of the opportunity costs of regulation.

The APVMA is mindful that the objective of the Commission's study outlined in item four of the terms of reference is to examine the efficiency and effectiveness of current chemicals regulation

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3 Information on APVMA committee structures is available from the APVMA website at http://www.apvma.gov.au/about_us/committee.shtml.

4 A guideline to the type of information the APVMA routinely publishes about registration applications is available from the APVMA website at http://www.apvma.gov.au/registration/downloads/DP_transparency_guideline.pdf.

5 Information on the APVMA's Adverse Experience Reporting Program is available from the APVMA website at http://www.apvma.gov.au/qa/vetaerp.shtml and http://www.apvma.gov.au/qa/agaerp.shtml.

frameworks in achieving economic, public health and safety, occupational health and safety (OH&S) and environmental outcomes. Australia's regulatory framework for agvet chemicals is world-class and directly comparable with the regulatory systems of other developed nations. It is a science-based system that upholds first world standards with respect to chemical products and their risk management. While reductions in data requirements or the rigour of assessment may be identified as means to increase chemical industry productivity, such action may not satisfy community expectations, particularly in terms of public health and environmental protection and may be offset by threatened access to vital trade markets, which is a core basis of current policy objectives.

The APVMA has approached this submission from the perspective of achieving incremental improvements in the efficiency and effectiveness in the delivery of current policy objectives. The focus is on increased co-operation and beneficial partnerships, rather than producing efficiencies through a reduction in regulatory standard or rigour.

3 Benchmarking APVMA performance

In 2005 the APVMA sought to benchmark key aspects of its operations against those of its counterparts in other countries. Despite the differences in regulatory activities and statutory responsibilities between the various agencies, the informal benchmarking study showed that the APVMA compared favourably with the equivalent Canadian, United States and United Kingdom regulatory authorities in terms of application fees, timeframes and timeframe performance. These results supported the outcomes of an earlier formal benchmarking study conducted in 1998 by Health Canada on behalf of the Pest Management Regulatory Agency (PMRA), which compared functions, application throughput, decision timeframes and costs of the pesticide regulatory systems in Australia, Canada, the United Kingdom and the United States.

The international competitiveness of the Australian regulatory system for veterinary chemicals has recently been confirmed by a qualitative survey commissioned by the International Federation for Animal Health and conducted by Business Decisions Limited. Business Decisions Limited's report, '*Benchmarking the Competitiveness of the Australian Animal Health Industry (March 2007)'*, found that chemical industry respondents perceived that the size of the Australian market is the biggest obstacle to innovation rather than the existing regulatory framework. This was in contrast to all other regions covered by the research where respondents identified the regulatory framework as being the biggest obstacle to innovation.

In 2006 the APVMA was subject to an extensive performance audit by the Australian National Audit Office (ANAO) which assessed whether the APVMA was delivering its key regulatory functions effectively. The performance audit report[6] acknowledged the various initiatives the APVMA had introduced in recent years to improve the effectiveness of its operations and made six recommendations. The APVMA welcomed the report and is implementing each of the recommendations. This is discussed further in Section 8, *Current Regulatory Reform Activities*.

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6 ANAO, *Regulation of Pesticides and Veterinary Medicines—Australian Pesticides and Veterinary Medicines Authority* (available at http://www.anao.gov.au/uploads/documents/2006-07_Audit_Report_14.pdf).

4 Previous reviews

4.1 Pesticide use in Australia

In 2002 the Australian Academy of Technological Sciences and Engineering (AATSE) released the report, *Pesticide Use In Australia* (Radcliffe Report), authored by Dr John Radcliffe[7]. The report was delivered just over a decade after the 1990 Senate Select Committee inquiry into agvet chemicals, *Report of the Senate Select Committee on Agricultural and Veterinary Chemicals in Australia*. It addressed contemporary trends in the use and application of pesticides, the impact of pesticides and their residues on public health and the environment, regulatory processes and their transparency as well as considering the impacts of genetically modified material on pesticide usage. The report aimed to provide an update for policy-makers since the Senate Select Committee inquiry.

The report's scope was limited to the rural use of agricultural chemicals and did not consider veterinary medicines or other products regulated by the APVMA and used in the domestic or urban environment. However, the report did draw a number of conclusions of potential relevance to this study. It recommended that:

- There is justification on economic policy grounds to have government intervention in a pesticide regulation system;
- A comprehensive and integrated pesticide usage reporting system be established to ensure the integrity and quality of Australia's agricultural produce. The report also concluded that such reporting systems should be able to facilitate rigorous cost/benefit analysis of the value of pesticide use in production systems and to enable evaluation of proposed future regulatory changes;
- Industries should closely examine the benefits that may be accrued from the adoption of Best Management Practices and ISO accreditation for production systems that are developed in response to such standards. The report also discussed the future importance of environmental management system codes of practice and indicated that they would become as important as food safety and quality assurance schemes;
- The regulatory processes for the assessment of pesticides for registration are comparable to those of most advanced western countries in terms of ensuring that the risks of potential to harm human health are minimised;

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[7] J C Radcliffe, *Pesticide Use in Australia*, Australian Academy of Technological Sciences and Engineering, ANL publishing, 2002. (available at http://www.atse.org.au/index.php?sectionid=199)

- Australia's food safety monitoring programs are comparable with those of other advanced western countries, but to provide continuing assurance to consumers and trading partners, continual monitoring of residue levels in produce is appropriate;
- The assessment of pesticides by the APVMA appears to be an effective and well conducted process that uses internationally accepted principles of risk assessment;
- Legislative requirements to protect manufacturing workers and farm applicators are complex and overlapping;
- A comparative analysis between the states and territories should be initiated to assess the outcomes and effectiveness of the control-of-use mechanisms used in the respective jurisdictions. The report identified that variation between the states and territories in their management of the control-of-use of pesticides as a concern and recommended that harmonisation be sought as a matter of urgency. Notably, the report focussed on harmonised outcomes with legislation established to agreed standards capable of consistent adoption and enforcement; and
- Food Standards Australia and New Zealand (FSANZ), which was being created at the time, in consultation with the APVMA should rapidly develop and issue a single Australian standard for MRLs for food and livestock feeds.

The report also discussed the need for an adverse effects register to be established for pesticide impacts on both human health and the environment. The APVMA has subsequently established and promoted its Adverse Experience Reporting Program (AERP) for agricultural chemicals. Further, the report's discussion of the respective roles and regulatory responsibilities of the Office of the Gene Technology Regulator (OGTR) and the APVMA has been addressed through the development of procedures and processes between those agencies, including legislative provisions and requirements.

4.2 A National Risk Management System for Agvet Chemicals—positioning for the future

In 2002 the APVMA commissioned the Allen Consulting Group to report on positioning and reform activities that may be required for the agvet regulatory and chemicals management system to meet future needs and challenges. The report, *A National Risk Management System for Agvet Chemicals—Positioning for the Future* (Allen Report)[8], delivered in September 2002, built on the AATSE report. It considered that the performance of the total agvet chemicals regulation system (encompassing assessment, registration, labelling, control of use, user training and accreditation,

[8] Allen Consulting Group, 'A National Risk Management System for Agvet Chemicals—Positioning for the Future', *A strategic review for the National Registration Authority for Agricultural and Veterinary Chemicals*, 2002. (available at www.allenconsult.com.au)

stakeholder engagement and confidence and access to information) was dependent on the way all the components operated together (frameworks). Although the APVMA does not have direct responsibility for policy-making, the review aimed to provide an objective perspective and view to assist policy makers.

The report identified a number of key drivers of future regulation. These key drivers were based on an exhaustive review of the available literature on agvet chemicals and their regulation, as well as an extensive consultation process with national and international stakeholders. The identified drivers include:

- community attitudes to the use of chemicals;
- technological advances that facilitate the development of safer chemistries and the impact of genetically modified crops on chemical usage;
- developments in the chemical industry, particularly the consolidation of multi-national companies, with the potential to impact on access to the latest agvet chemicals in Australia;
- chemical usage trends and needs in the agricultural sector;
- trade requirements and the need for international confidence particularly in agricultural exports; and
- the ongoing need for reform to ensure that regulation is optimal for Australia's needs.

The report also compared and contrasted the Australian regulatory system and its drivers with developments in North America and Europe where there had been a trend for increased and more sophisticated regulation. The report's view was that the experiences in these larger and somewhat more established markets could provide 'key messages' for future developments in Australia.

From an analysis of future regulatory drivers the Allen Consulting Group identified seven principles it considered essential for the design of an ideal agvet chemicals regulation and management system. They are:

- *a seamless system* with improved integration between registration and control of use functions;
- *strong feedback loops* to better inform decision-making;
- *flexibility to respond to emerging issues*, facilitating responsiveness to emerging issues such as technological advances;
- *provision for continuous improvement*, facilitating and encouraging the employment of the latest scientific knowledge both in terms of products and agricultural practice;
- *confidence in the regulatory and management process* through adequate provision for transparency and consultation;
- *effectiveness and efficiency* with the regulatory impost being the minimum necessary to achieve the public interest policy objectives; and
- *international confidence*, to ensure continued access to vital export markets.

The Allen Consulting Group concluded that the reforms of the 1990s that led to the establishment of the NRS and the APVMA constituted an important step towards an integrated national risk management system for agvet chemicals. However, to deal with future drivers and challenges the report recommended structural solutions and proposed four options for structural integration. Two of the options involved horizontal integration, either through a new agency with broader functions, or through the consolidation of all functions relating to agvet chemicals into a single department. The other two options involved vertical integration, with either one Australian Government agency taking responsibility for the management of all agvet chemical issues, such as those currently undertaken by the APVMA as well as the states and territories, or alternatively with integration achieved via the adoption of national operating principles.

Other reviews of agvet chemical regulation, such as *OHS Implications of Agvet Chemical Regulation* [9], have in many ways agreed with the Allen Report in considering integrated regulatory or risk management frameworks for improving the effectiveness of regulation. Indeed, with regard to the management of OH&S risks Healy and Gunningham argue that the chemicals management framework, at that time, reduced the functional capacity of regulators within the agvet chemical arena to coordinate programs and resources and reach all stakeholders.

4.3 Australian Agricultural and Veterinary Chemicals Management System—a report to Government by the APVMA on recent reviews of the system

In response to the Radcliffe and Allen reports the APVMA published a report entitled, *Australian Agricultural and Veterinary Chemicals Management Syste*m, *A Report to Government by the APVMA on recent reviews of the system*—June 2003 (copy enclosed)[10]. That report set the Radcliffe and Allen findings in the context of the then (1998) Agriculture and Resource Management Council of Australia and New Zealand's (ARMCANZ) National Strategy for Agricultural and Veterinary Chemicals (which had been transformed into a risk management strategy underpinning PSIC's priority policy areas of work) and encompassed consideration of an Environment Protection and Heritage Council (EPHC) report, *Toward Ecologically Sustainable Management of Chemicals In Australia*, that had been released at that time.

PSIC considered the reports and made a number of recommendations through PIMC to improve the existing system. It was determined that improved integration within the system could be most

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9 Healy and Gunningham, 'OHS Implications of Agvet Chemical Regulation', *National Research Centre for OHS Regulation Working Paper 8*, 2003. (available at http://ohs.anu.edu.au/publications/pdf/OHS%20implications%20of%20agvet%20regulation.pdf)

10 The report is available from the APVMA website at http://www.apvma.gov.au/publications/downloads/cox.pdf.

efficiently achieved through the adoption of national operating principles with arrangements to facilitate improved data collection, performance measurement as well as better user competencies. It was believed that the adoption of national operating principles was the most appropriate method of achieving improved consistency in regulatory outcomes.

4.4 Report of the Taskforce on Reducing Regulatory Burdens on Business—rethinking regulation

The Report of the Taskforce on Reducing Regulatory Burdens on Business (Banks Report)[11] made five recommendations relating to agvet chemicals. All the recommendations of the taskforce were addressed in a comprehensive Australian Government response[12].

Noting that the current study is one of the outcomes of the Banks Report Recommendation 4.58 (to develop an integrated national chemicals policy in order to inform the COAG[13] Ministerial Taskforce), the APVMA has been actively participating in a number of activities supporting the recommendations:

- *Recommendation 4.56: Implement performance indicators and targets for regulators.* In support of this recommendation, the APVMA develops a comprehensive Operational Plan each year and publishes it on its website[14]. The Operational Plan contains over 80 performance measures and targets. Performance against those measures and targets are reported to the APVMA consultative committees and published in the APVMA Annual Reports[15].
- *Recommendation 4.57: Reduce variation from international standards.* In support of this recommendation the APVMA has deepened its involvement in international forums such as OECD[16] and VICH[17] and has strengthened international linkages through signing memoranda of understanding with a number of its international counterparts. As 'leveraging international

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11 The Report of the Taskforce on Reducing Regulatory Burdens on Business is available at http://www.regulationtaskforce.gov.au/finalreport.

12 A copy of the Australian Government's response is available at http://www.treasury.gov.au/documents/1141/RTF/Reducing_Regulatory_Burdens_on_Business_Final_Government_Response.rtf

13 Council of Australian Governments

14 The APVMA's 2007/08 Operational Plan is available at http://www.apvma.gov.au/publications/downloads/operationalplan07.pdf

15 The APVMA's Annual Reports are available at http://www.apvma.gov.au/publications/annual%20reports.shtml.

16 Organisation for Economic Cooperation and Development

17 International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products

linkages' is a specific issue for the current study more detailed comments are provided in Section 6, *International Linkages.*

- *Recommendation 4.59: Improve the management of security sensitive chemicals*. The APVMA is currently working with other government departments and industry to develop policy on this issue for COAG consideration.
- *Recommendation 4.60: Improve administration of low risk chemicals*. In support of this recommendation the APVMA has worked with PSIC to develop faster and easier mechanisms for the regulation of low risk chemicals. The responsibility for reviewing arrangements for such chemicals rests with PSIC, at which the APVMA is an observer. Further, PSIC is working to define the scope of the products regulated by the APVMA that would avoid the need for registration by the APVMA of certain product groups. These reforms are discussed further in Section 8, *Current Regulatory Reform Activities*.

4.5 Annual Review of Regulatory Burdens on Business (Primary Sector)

The APVMA notes the Commission's comments in the draft report of the Annual Review of Regulatory Burdens on Business (Primary Sector) that the burden imposed on the agricultural sector through the regulation of farm chemicals was raised more often in submissions to the review than any other concern[18]. The APVMA reiterates that this does not necessarily mean that the regulation of farm chemicals is the most significant burden on the agricultural sector and we wish to point out that a number of the submissions that raised concerns over chemical regulation were provided by associations from the manufacturing and distributive sector and focussed on burdens to that sector, rather than burdens to farmers and other primary sector businesses.

While the APVMA acknowledges that submissions to the Annual Review raised some relevant issues particularly in the area of consistency in the national regulatory framework, several contained factual inaccuracies that were addressed in the APVMA's initial submission to that review. The APVMA also provided additional clarity and background information on several issues at that time.

The APVMA notes in draft response 3.27 of the Annual Review that issues raised in relation to agvet chemical regulation through the Primary Sector review will be referred to the current Chemicals and Plastics Study, and we refer the Commission to the APVMA's submissions to the Annual Review[19]. Our previous submissions provide a comprehensive response to matters raised in

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18 Productivity Commission Draft Research Report—*Annual Review of Regulatory Burdens on Business: Primary Sector,* 12 September 2007. Page XVIII.

19 The APVMA submissions (Submission 42 and DR65) to the Annual Review of Regulatory Burdens on Business (Primary Sector) are available at http://www.pc.gov.au/study/regulatoryburdens/docs/submissions.

the Annual Review, a number of which have been re-presented to the Commission as submissions to the current study, and further comment on a number of these issues is provided in Section 8 *Current Regulatory Reform Activities*. Similarly, the APVMA notes draft response 3.8 that existing reform activities between the Australian Quarantine Inspection Service (AQIS) and the APVMA will reduce any duplicative requirements for the importation of veterinary vaccines and as such we will not address that matter further here.

As discussed in the APVMA's submission to the Annual Review, following the release of the draft research report, we note that no submissions contained measures of the quantitative effect of regulation on business. A lack of quantitative evidence regarding the size of the unnecessary burden from regulation restricts the ability of the Commission to assess the regulatory burden. Further, we note the Commission's view that all regulation has a cost but that unnecessarily burdensome regulations, the focus of the Annual Review and of the current study, are a smaller subset of costs that are over and above the necessary costs inherent in meeting policy objectives[20].

While it is difficult to separate the unnecessary costs of regulation from the underlying or necessary costs, access to quantitative data would better inform governments, in light of the diverse perceptions held between different stakeholders, on the extent of the excessive burden regulation imposes. We reiterate our support for the promotion of further research in the area of quantitative cost effects of regulation. Such cost estimates would better inform governments on the actual as distinct from the perceived effects of unnecessary regulation on business in both the primary sector and the chemicals and plastics industry.

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[20] Productivity Commission Draft Research Report, op. cit., p. XXI.

5 Current regulatory arrangements

Australia like other developed nations has a high reliance on the use of chemicals to assure its food supply, for medicines and for industrial and consumer products. Acknowledging the fact that chemicals are an integral part of our lives, the fundamental rationale for the regulation of chemicals in Australia is to protect the health of people and to prevent detrimental effects to the environment (to protect the 'public good').

Chemical regulation fulfils this protective role by performing six key functions:

1. hazard assessment by determining the inherent hazard of chemicals;
2. exposure assessment by determining the type and extent of the exposure of chemicals to humans and the environment;
3. risk assessment by determining the likelihood of exposure to the hazardous chemical, and the impact of such exposure;
4. the setting of standards;
5. risk management and communication by determining how to manage the risks of chemicals through the registration of products, approval of labels, issuing of permits and licences, as well as the public consultation mechanisms for registration and chemical review; and
6. enforcement and control of compliance with laws and standards.

According to the nature of the Australian constitution, the regulation of chemicals is a state and territory responsibility. The Commonwealth is only formally involved if the states have either referred or conferred legislative powers to the Commonwealth or an individual authority (as in the case of the agvet NRS[21]) or have agreed to a standard setting role by the Commonwealth as in the case of the industrial chemicals framework.

Regulation of agvet chemicals

Before a chemical product can be supplied or otherwise made available for use the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code) requires the APVMA to be satisfied that the

[21] Under the NRS arrangements the states have conferred legislative powers on the APVMA Body Corporate.

use of the product in accordance with its instructions would:

i. not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and

ii. not be likely to have an effect that is harmful to human beings; and

iii. not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and

iv. not unduly prejudice trade or commerce between Australia and places outside Australia; and

v. be effective.

Furthermore, before registering a chemical product the APVMA must be satisfied that the label for the product has adequate instructions for the product's safe and effective use.

These legislative criteria address the key public health, OH&S and environment protection goals of regulation and encompass the first five regulatory functions listed above. While the APVMA has some enforcement and compliance responsibilities with respect to the manufacture, supply and quality of chemical products (further information on the APVMA's functions and activities is provided in Appendix A), under the current arrangements the enforcement of use in accordance with label instructions is a state and territory responsibility.

5.1 Australian Government regulatory frameworks

Although the Commission's study is limited to industrial and agvet chemicals, the APVMA believes that to comprehensively assess the effects of regulation on the chemicals and plastics industry, consideration of the roles and functions of the four key national regulatory bodies[22] is warranted. This approach is recommended to fully appreciate the different interests and scope of current regulatory frameworks and facilitate an informed discussion of potential reforms to achieve improved efficiencies in regulatory process.

As noted in the Issues Paper, at the Australian Government level, chemicals are regulated with regard to their end-use with regulatory regimes for industrial chemicals, agvet chemicals, medicinal products and pharmaceuticals, and food additives and contaminants. These arrangements reflect the concept that the case for regulating is dependant on both hazard and risk, with risk relating closely to use and thus the potential exposure to people and the environment.

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[22] The four key regulatory bodies are the Therapeutic Goods Administration (TGA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the APVMA and FSANZ.

From a regulatory perspective it is the use and potential exposure pathways that drive the type and nature of regulatory assessment. Table 1 highlights the differences in terms of regulatory functions for the various chemical types. Assessment components differ between the regulators as they are commensurate with the risk and potential exposure associated with the intended use. Similarly the detail of assessment of the in-common components also varies according to the potential for exposure. This is why information requirements may vary between regulators for the same assessment component (e.g. environment). Such differences are appropriate where exposure potential and risks of exposure differ.

In the case of agvet chemicals, they are intentionally applied to the environment and food. This means that the potential for exposure and thus risk to people and the environment is significantly different to that experienced in the other chemical industry sectors.

APVMA arrangements for obtaining scientific advice from Government departments

Under the current regulatory arrangements a regulator such as the APVMA is the primary agency for chemical approval or registration. That is, a proponent or sponsor of a chemical product (i.e. an applicant) makes an application to the APVMA to register a chemical product, submits the necessary supporting information and the APVMA organises and manages the specialist assessments that are relevant to the registration proposal. This consolidates the application process and places the administrative burden of organising and quality assuring the advice that is necessary to make a regulatory decision with the APVMA.

Currently the APVMA has formal service-level arrangements with the Australian Government Department of Health and Ageing (DoHA), Office of Chemical Safety (OCS) and the Australian Government Department of the Environment and Water Resources (DEW), Environmental Quality Division for the provision of advice on public health and environmental issues respectively, to the APVMA. The APVMA also engages state government departments and private consultants for the provision of advice in relation to product efficacy and for crop and animal safety.

Table 1 Summary of national regulatory structures

		TGA	APVMA	NICNAS	FSANZ
Chemicals regulated		**Human medicines**	**Agvet chemicals**	**Industrial chemicals**	**Food additives and contaminants**
Hazard and exposure assessment component	Toxicology and Public Health	TGA	OCS	NICNAS	FSANZ
	Occupational health and safety	Not relevant	OCS	NICNAS	Not relevant
	Environment	Not relevant	DEW	DEW	Not relevant
	Residues[23]	Not relevant	APVMA	Not relevant	FSANZ
	International trade	Not relevant	APVMA	Not relevant	Not relevant
	Product chemistry and manufacturing	TGA	APVMA	Not relevant	Not relevant
	Efficacy	TGA	APVMA and states	Not relevant	Not relevant
Risk assessment component and standard setting		TGA	OCS / DEW / APVMA	NICNAS	FSANZ
Risk management and communication component		TGA	APVMA	NICNAS	FSANZ
Outcomes of risk management component	Assessment products	Registered Product Approved label	Approved active constituent Registered Product Approved label	Chemical entered on AICS Recommendations provided to ASCC and state authorities	Food Standard
Users	Direct end-users	Medical professionals	Farmers, veterinarians	Manufacturing and distributive sector	Consumers
	Indirect end-users	Consumers	Consumers	Consumers	
Enforcement and control		TGA and states	APVMA and states	NICNAS and states	states

[23] The residues component is relevant to human health and international trade.

5.2 Adoption of Australian Government standards and regulatory decisions by states and territories

Under the current arrangements regulation is largely 'delivered' by the states and territories. That is, the outcomes or assessment products of the Australian Government regulatory bodies in Table 1 are applied or adopted by the states and territories. Mechanisms of adoption vary between jurisdictions and between regulatory structures. However, broadly speaking adoption is either:

- mandatory, by directly adopting the national standard and dealing with it in identical ways to other jurisdictions. For example all states and territories' legislation automatically recognises the registration of an agvet chemical by the APVMA, such that agvet chemical registrations by the APVMA are national registrations (i.e. uniform and seamless adoption); or
- semi-mandatory, by adopting the national standard and dealing with it in separate ways to other jurisdictions. For example all states and territories' legislation automatically recognises the approval of a label by the APVMA but the respective jurisdictions may enforce adherence to label instructions more leniently or strictly; or
- discretionary, where a jurisdiction may choose to adopt a standard or parts of the standard and may then choose to deal with it in separate ways to other jurisdictions. For example the states and territories are not required to implement recommendations made by NICNAS for industrial chemicals and the controls available to the states and territories to manage those chemicals often differ.

Under the arrangements of the NRS for agvet chemicals any change to the Agvet Code automatically effects a change to each state and territory agvet code without the need for involvement of the parliament of each state and territory. The agreement that established the NRS does however require the agreement of the states and territories via PSIC before changes to the Agvet Code can be effected.

For agvet chemicals, state and territory governments currently are responsible for regulating chemical use through control of use legislation. While the mode of enforcement of the label instructions approved by the APVMA is semi-mandatory and thus regulatory requirements vary between jurisdictions, they generally include the following components delivered in varying degrees:

- basic training requirements for users;
- licensing of commercial pest control operators and ground and aerial spray operators;
- residue monitoring; and
- arrangements to facilitate the safe use of chemicals, including the use of codes of practice, spray drift policies and guidelines and other user awareness raising initiatives.

Additionally, at the state and territory level there may be additional tiers of regulation that impact on the use of chemicals relating to public health, OH&S and environmental protection. For example

chemical users on farms may be required to comply with control of use regulations and OH&S regulations that overlap. Confusion and non-compliance may result when compliance with label instructions does not necessarily result in compliance with OH&S regulations[24].

5.3 Cross-portfolio and national linkage mechanisms

As illustrated above, the business of chemicals regulation involves various government agencies, portfolio departments and the interaction between Australian Government regulators and the states and territories. To co-ordinate this interaction a number of linkage mechanisms exist to assist the delivery of chemicals regulation at and between the various levels of government.

Australian Government

Departments responsible for national chemical policy and national regulators currently interact through the Clearing House of Commonwealth Agencies for Chemical Safety (Chemicals Clearing House), which was established as an *ad hoc* Inter-Departmental Committee by the Ministers for Environment, Health, Primary Industry and Industrial Relations in 1992. The Chemicals Clearing House has an international focus and provides an opportunity for collaborative cross-portfolio input to the development and implementation of international chemical standards and regulations. The regulators and policy departments also regularly communicate *ad hoc* on specific chemicals issues relating to the operation of chemicals regulation and the policy of chemicals regulation on specific issues, such as security sensitive chemicals and nanotechnology.

Australian Government, state and territory linkages

Cross-portfolio linkages and Australian Government, state and territory linkages are built in to the NRS via the membership of PSIC. PSIC's membership comprises representatives from:

- Australian Government Department of Agriculture, Fisheries and Forestry (DAFF)
- Australian Government and state and territory departments responsible for primary industries
- New Zealand Food Safety Authority (NZFSA)
- Commonwealth Scientific and Industrial Research Organisation (CSIRO)
- Australian Pesticides and Veterinary Medicines Authority (APVMA)

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[24] Healy and Gunningham, op. cit.

- Environment Protection and Heritage Council (EPHC)
- Workplace Relations Ministerial Council
- Australian Health Ministers' Advisory Council (AHMAC).

PSIC coordinates national approaches for managing potential risks to food safety, public and occupational health, trade and the environment from agvet chemicals, fertilisers and animal feedstuffs, environmental contaminants and residues in primary production systems. PSIC's cross-portfolio membership which is provided by representation from other Ministerial Councils, facilitates awareness of policy approaches in other portfolios. Its state and territory membership facilitates linkage with those jurisdictions and provides an avenue for their input to regulatory policy. With respect to the management of agvet chemicals this linkage is particularly important to aid the coordination of risk management between the Australian Government and state and territory governments.

In addition to PSIC the APVMA's RLC provides another avenue of Australian Government and state and territory government connection. RLC comprises of representatives from state and territory departments with responsibility for administering control of use. It provides a forum to facilitate alignment of the agvet chemical control objectives between the APVMA and states and territories for the ongoing development and operational coordination of the NRS. It also provides an avenue for consultation on the development of operational policies, guidelines and protocols. Furthermore, the Control of Use Forum associated with RLC provides a mechanism to facilitate state-to-state linkages.

Inter-state linkages

For agvet chemicals there are no other inter-state linkage mechanisms, apart from RLC and PSIC to aid in the delivery of nationally consistent risk management outcomes.

Intra-state linkages

The APVMA is aware that at least one state, Western Australia, has a formal committee structure to coordinate the various portfolios' approach to pesticides management. That statutory structure, the Pesticides Advisory Committee, is established by Section 246B of the *Health Act 1911* and includes membership from the a number of Western Australian state departments including the Department of Health, the Department of Environment and Conservation, WorkSafe, the Chemistry Centre, the Department of Food and Agriculture and the Department of Water. The committee meets regularly to advise the Western Australian Government on pesticide issues.

Although it is understood that the role of the Pesticides Advisory Committee is largely an advisory one to the Western Australian Government on pesticide issues, such a structure does seem attractive in terms of improving efficiencies in the delivery of regulation. The APVMA is aware that the Western Australian Government has recently undertaken a review of the legislative and policy arrangements regulating the use of pesticides in that state[25] and that a key outcome of that review is the retention of a coordinating committee but with greater representation from state regulatory agencies.

5.4 Cost recovery arrangements of the APVMA

The APVMA notes that the appropriateness of the current financial costs to applicants and cost recovery arrangements for the registration of chemicals has been raised in the Issues Paper. Ultimately the cost recovery arrangements for chemicals regulation is a policy matter for the Australian Government. Since 1996 the APVMA has been operating on a full cost recovery basis. This arrangement was determined by the Australian Government in conjunction with all state and territory governments and is set out in the agreement that establishes the NRS. As a consequence of the complex inter-governmental governance arrangements for the NRS, changes to the legislation and the over-arching policy framework, including the cost recovery arrangements, may only be made with the consent of all signatories to that agreement.

The last review of the APVMA's fee structure occurred in 2005 when a Cost Recovery Impact Statement (CRIS) considered various policy issues and fee options. The CRIS process included detailed and comprehensive consultation with the agvet chemical industry. The CRIS recommended that the cost of approvals and registration be subsidised with the applicant only paying 40 per cent of the actual assessment cost and the remainder being recovered across the life of the product via the levy on wholesale sales[26].

It is noteworthy that in its support for the nominal fee of 40 per cent of the cost of assessing applications, the then Signatories Working Group (SWG)[27] considered that a higher level of cost recovery via the application fee could be a significant disincentive for new products and other innovation into the market, particularly in the case of small businesses and low volume chemical products. Various sections of the agvet chemical industry have opposed the 40 per cent subsidisation level and the use of the levy as the balancing factor and argue that this constitutes inappropriate

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25 The Review of Pesticide Legislation and Policies in Western Australia is available at http://www.health.wa.gov.au/publications/documents/Review%20of%20Pesticide%20Legislation%20WA.pdf

26 Information on fees and levies is available from the APVMA website at http://www.apvma.gov.au/registration/feesmain.shtml

27 The Signatories Working Group was a sub-committee of PSIC.

cross-subsidisation. Other submissions received as part of the CRIS process proposed application fees varying from zero to 100 per cent of the cost of assessing the application.

The cost recovery arrangements of the APVMA are due for review by the end of the 2007–08 financial year. This process will be managed by DAFF.

6 International linkages

The APVMA places a high importance on developing relationships with its overseas counterparts and actively engages with comparable regulators in other countries to facilitate improved efficiencies wherever possible. Such international cooperation is intended to harmonise data assessment procedures and data requirements between comparable regulators, facilitate improved alignment and 'portability' of scientific data with respect to chemical products, build confidence and enhance the efficiency and effectiveness of the respective regulator's operations.

The APVMA agrees that international harmonisation or alignment, where possible and appropriate, offers significant benefits in terms of efficiency and cost effectiveness not only for the chemicals and plastics industry but also for the industries reliant on the availability of contemporary chemicals, such as the primary industry.

To facilitate a comprehensive analysis on the how best to leverage international linkages, it is useful to define the breadth of the topic. Broadly speaking 'international standards and agreements' from Recommendation 4.57 of the Banks Report, can be grouped into:

- data requirements including guidelines and other information requirements;
- submission or "dossier" formats;
- risk assessment methodology on either specific risk areas or product groups;
- risk assessment reports on specific risk areas (e.g. toxicology);
- combined risk assessment reports for specific products that cover all risk areas;
- regulatory decisions/risk management (product registration or label approval, licensing and setting of standards and regulatory limits); and
- publication of regulatory assessments using international formats.

These elements are further detailed in Appendix B.

When considering the acceptance of international data, the APVMA may[28] and does take into account information generated overseas where it is appropriate to do so. Differences in the use of a particular chemical product and in environmental factors that affect the use of the product in Australia and overseas can however impact on the relevance of information that is generated overseas.

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[28] Section 160 of the Agvet Code allows the APVMA to take account of information generated overseas in its decision-making to the extent that the information is relevant.

It is important to note that in certain situations divergence from international standards may be both justified and provide a public benefit to the health and safety of the Australians or the environment. For example the Food and Agriculture Organisation (FAO) specification for the chemical paraquat requires the inclusion of an emetic (a chemical that induces vomiting) in chemical products that contain paraquat. However, DoHA advise that inducing vomiting is not recommended for many poisons and therefore the inclusion of an emetic is not required. A second example is that the adoption of all elements of GHS, developed through the United Nations, may not be appropriate for or benefit the current risk-based labelling system for agvet chemicals. These examples highlight the need for clear and systematic strategic analysis when considering the adoption of international standards to the Australian situation.

The APVMA's key international involvement and linkage activities are summarised below.

Pesticide work-share projects

The APVMA is involved in a number of international work-share projects through the OECD. Under these work-share arrangements individual countries take the lead on specific aspects of the regulatory assessment and following extensive peer review by the partners in the work-share project, provide a hazard assessment report to all the participants. A country such as Australia then takes that hazard assessment and in conjunction with its advising agencies (OCS and DEW in Australia) sets standards and applies risk mitigation. The setting of standards such as public health standards and the application of risk mitigation are country specific due to societal differences in the acceptance of risk. Within this context the APVMA accepts evaluations conducted by other competent regulatory authorities and uses them to make regulatory decisions.

It is important to note that the use of overseas assessments in this manner does not negate the need for the relevant data to be submitted in Australia. It is critical to the success of international work sharing, and more importantly to the protection of intellectual property that applicants submit full copies of the data submitted to overseas authorities for the purposes of their evaluation. This is the internationally agreed practice. The APVMA cannot rely on a published evaluation of another country if the data upon which that evaluation is based has not been submitted to the APVMA. To do so could potentially breach our obligations with respect to intellectual property protection. Work-shares have evolved as a result of intensive OECD work, with Australian Government participation, on the development of a number of parameters including general guidance on work-shares and uniform templates for data presentation.

Work-shares are expected to eventually lead to Australian Government acceptance of OECD-consistent monographs on hazard assessment developed by other regulator work-shares without the need for the Australia Government to necessarily be involved in the work-share itself. This would provide a significant productivity gain for chemical industry registrants who have an international focus.

VICH veterinary medicines data requirements and guidelines

The APVMA participates as an observer in the VICH program (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products[29]), which is a trilateral program aimed at harmonising technical requirements for veterinary product registration. The APVMA data requirements documents[30] recognise a number of the VICH guidelines which facilitates improved international portability of registration data submissions.

The APVMA has led and supported other Australian Government departments to participate in most VICH working groups, including the development of guidance on Phase I and II data requirements for environmental toxicology, toxicology guidelines, antimicrobial resistance and currently, involvement in guidance for residues and metabolism guidelines.

Bilateral agreements

In addition to its active involvement with the OECD and VICH, the APVMA has invested significant effort into direct international engagement with similar regulatory authorities to optimise international consistency, information sharing and harmonisation where possible. The APVMA has signed a Memorandum of Understanding (MOU) with the Agricultural Compounds and Veterinary Medicines group (ACVM) of NZFSA, the United States Food and Drug Administration (USFDA), the United Kingdom Pesticides Safety Directorate (PSD), the United Kingdom Veterinary Medicines Directorate (VMD) and the Canadian Veterinary Drugs Directorate (VDD). Under its MOU with the ACVM group of the NZFSA, the APVMA is currently undertaking a collaborative project comparing data requirements and assessment processes between the two countries, with a view to improving alignment.

Other leading positions in international engagement

Further to its international engagement with respect to registration activities, the APVMA chairs an OECD Expert Group on Minor Use which seeks to develop ways to share international data, thereby reducing the costs to Australian growers of producing data to support minor uses. Such linkages not only work to improve efficiencies in regulatory process, but also work to deliver outcomes supporting Australia's primary industry.

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29 Further information on VICH can be obtained at http://www.vichsec.org/

30 The APVMA publishes its data requirements in a publication titled Manual of Requirements and Guidelines (MORAG). See paragraph 8.1.

The APVMA also actively participates in multilateral international forums such as the Codex Alimentarius Commission (Codex), the Joint Meeting on Pesticides Residues (JMPR) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to contribute to and influence international policy with respect to residues in food. Such activities are important in ensuring access to international trade and supporting Australia's primary industry.

7 Alternatives to regulation

The APVMA acknowledges that self-regulatory schemes have a place in the overall chemicals regulation framework. Indeed, effective self-regulation programs can reduce the need for government involvement. Programs such as Agsafe[31] and Responsible Care[32] require adherence to codes of practice and use tools such as accreditation to facilitate compliance. However, a potential flaw of self-regulatory schemes requiring accreditation is the management of non-compliance, particularly where authorisation activities may be seen as limiting the market entry of new participants and therefore anti-competitive.

Studies of self-regulation schemes have suggested that without the authority of explicit, lawful sanctions effective industry self-regulation is difficult to maintain[33]. The success of self-regulation depends on the penalties that may result from non-compliance and the risk of exposure. Some have argued that explicit sanctions are necessary to prevent opportunistic behaviour and to prevent competitors free-riding off the efforts of industry leaders[34]. In contrast, others argue that the need for sanctions is overstated as self-regulation can control behaviour through more informal means of coercion, the transfer of norms and the diffusion of best practice[35].

The mildest form of self-regulation involves the development and promulgation of industry codes of practice. The APVMA fully supports the development of industry codes of practice that are consistent with or supplement existing legislation. More rigorous self-regulatory regimes involve policing of these codes with sanctions for non-compliance. At the extreme, they could involve expulsion of the violator either from the company in question or from the industry.

There are challenges to the development of self-regulatory schemes as alternatives to government intervention and regulation. Where such programs are implemented through industry associations, market contributors who are not members of the association have no obligation to comply and may ignore association programs. While chemical industry associations generally represent companies that collectively control a significant proportion of market-share, they do not represent all

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31 Further information on Agsafe can be obtained at http://www.agsafe.com.au/.

32 Further information on Responsible Care can be obtained at http://www.responsiblecare.org.

33 For example, see King and Lenox's *Industry self-regulation without sanctions: The chemical industry's Responsible Care Program*, available at http://www.stern.nyu.edu/bes/papers/selfreg.pdf .

34 A Grief, 'Microtheory and recent developments in the study of economic institutions through economic history', Kreps, D and Wallis, K (Eds.), *Advances in Economic Theory and Econometrics* (Volume II), Cambridge, Cambridge University Press, 1997, pp. 79-113.

35 J Nash, & J Ehrenfeld, 'Codes of Environmental Management Practice: Assessing Their Potential as a Tool for Change', *Annual Review of Energy and Environment*, vol. 22, 1997, pp. 487-535.

companies in a market sector and potentially leaving some operators outside the scope of the self-regulatory scheme. In addition, the success of self-regulation depends on the desire of association members to comply to avoid penalties or loss of association membership. Where market failure has happened or is likely to happen and no industry self-regulatory schemes have been developed, the government may need to regulate immediately before any self-regulation is initiated in order to avoid further market failure.

The APVMA's experience in this area is that industry associations have not proposed suitable self-regulatory schemes that would be likely to replace existing regulation, that would avoid the need for proposed regulation or that could be applied consistently across the industry. As an example, the introduction of regulation regarding the quality of active constituents in agricultural chemicals (the Ag QA Scheme) was brought about by concerns over the quality of active constituents used in chemical products. The chemical industry had not provided an industry-wide self-regulatory model to address industry compliance with active constituent quality. Due to ongoing concerns about active constituent quality, the APVMA through its 'compliance strategic reform' project (discussed in Section 8, *Current Regulatory Reform Activities*) is now proposing further regulatory control in this area to assure active constituent quality in chemical products.

While acknowledging the challenges, the APVMA encourages the chemical industry, through its industry associations, to coordinate its efforts to provide tangible alternatives to regulation that would meet the objectives of proposed or existing regulations and be consistently applied across industry sectors and market contributors.

8 Current regulatory reform activities—reducing regulatory burdens and barriers

The APVMA has proactively sought to reform its internal processes, structures and documents as well as to inform external reform agendas. The following operational reform activities and PSIC reform activities outline the major projects currently being undertaken. We have chosen to include the activities below to highlight those that are expected to have a direct effect on chemical and primary industry productivity, which is the emphasis of this study.

8.1 APVMA operational reform activities

The APVMA has been highly proactive in terms of developing initiatives and reforms to streamline its processes and create efficiencies in the delivery of its outputs. The current key priority areas for reform are outlined in the APVMA's 2007–08 Operational Plan (copy attached)[36].

Electronic submission of applications

In May this year the APVMA released its Electronic Application and Registration System (EARS) which offers the chemical industry the opportunity to electronically submit and monitor the progress of applications for the registration of agvet chemicals. The APVMA is the first regulator of its kind to have introduced such a facility. This innovation will create efficiencies for both the chemicals industry and the APVMA through streamlining the application process. Further information on EARS is available from the APVMA website[37].

It is important to note that the EARS software was developed 'in-house' by the APVMA's Systems Designs and Development group, which has proven to offer advantages in terms of cost-effectiveness when compared to a reliance on external consultancies for such projects.

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36 APVMA Operational Plan, op. cit.

37 Information on the Electronic Application and Registration System (EARS) is available at http://www.apvma.gov.au/media/mr0703.shtml.

Options for self-assessment

The APVMA believes that self-assessment of some aspects of applications by approved applicants offers opportunities to reduce regulatory burdens. To this end the APVMA is investigating the feasibility of a 'quality assurance' system that would allow approved registrants to make specified minor variations to registered products without the need for application to the APVMA. For some time the APVMA has had a system in place whereby minor variations to veterinary chemical product formulations in terms of non-active constituents are permitted with much reduced chemistry data requirements. The APVMA is looking to adapt a similar system for such variations in agricultural chemical products.

The APVMA is also currently investigating the feasibility of registrants separately seeking review of efficacy data by approved reviewers prior to making application to the APVMA. This proposal has significant potential to reduce the APVMA assessment time of applications as the APVMA could base its decision on the advice of the approved reviewer's report which would conform to set standards rather than conducting the review itself. Such a proposal, if feasible would also translate to lower APVMA application fees and timeframes.

Labelling

The APVMA has introduced a number of process reforms, which have greatly decreased the regulatory burden with respect to approval of labels. In October 2003 the APVMA issued a permit (PER6868) that allows registrants to make various administrative label amendments without the need for application to the APVMA. In November 2006 the APVMA issued a subsequent permit (PER9523) that allows registrants to vary the label with respect to net contents provided the contents are within an approved range without the need for application to the APVMA. In this respect, the regulatory burden related to labelling has been lessened since October 2003 with no apparent decrease in effective label control. The APVMA is currently developing further labelling reforms with the potential to broaden the type of label changes that could be made without application to the APVMA. In addition to these initiatives, the APVMA has introduced the electronic submission of printer's proofs of labels, which has delivered improved the efficiencies for the chemicals industry in terms of label approval.

Reducing Elapsed Time project

The APVMA acknowledges industry concerns over the timeliness of assessment processes and it has developed a comprehensive plan of over thirty initiatives, some of which are discussed in this section, that address each part of the application process from pre-application work by the applicant to the time of the regulatory decision by the APVMA. This project aims to reduce the time that

elapses (elapsed time[38]) between application to the regulator and product registration, thereby increasing chemical industry productivity by enabling faster legal supply to the marketplace and primary industry productivity by enabling faster access to necessary chemicals.

The project has both an internal and external reach and recognises that the chemical industry is also responsible for components of 'elapsed time' as identified in the ANAO Performance Audit Report. The ANAO noted that the quality of applications submitted by the chemical industry could be improved, with 74 per cent of pesticide and 76 per cent of veterinary medicine applications made to the APVMA containing errors or deficiencies. The ANAO criticised the APVMA for repeatedly giving applicants additional time to correct deficiencies, as it leads to a prolonged elapsed time for applications. It is however important to note that the ANAO found that due to APVMA initiatives, 98 per cent of applications received after 1 July 2005 were finalised within the statutory timeframe.

Compliance Strategic Reform project—appropriate tools and framework to take effective action against non-compliance by the chemical industry

The APVMA has initiated a project in consultation with the chemical industry to look at fundamental tools that can be used by the APVMA to enforce industry's compliance with legislation. While this will increase the regulatory burden for non-compliers, the reforms are expected to encourage a 'level playing field' and increase competitiveness for those industry members who comply with regulations.

APVMA Manual of Requirements and Guidelines (MORAG)

The APVMA has made a concerted effort to ensure that all its requirements documents and guidelines are available through its website. These have been consolidated in the respective Manual of Requirements and Guidelines (MORAG)[39] for agricultural and veterinary chemicals. Access to MORAG aims to increase industry productivity through ready availability of information on data requirements and expectations.

ANAO Performance Audit—implementation

In 2006 the ANAO conducted a performance audit of the APVMA. The extensive audit assessed whether the APVMA was delivering its key regulatory functions effectively.

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38 The differences between elapsed time and statutory timeframes are explained in Appendix C.

39 MORAG is available from the APVMA website at http://www.apvma.gov.au/industry/MORAG.shtml.

The ANAO examined APVMA arrangements 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 Performance Audit Report[40] acknowledged the various initiatives the APVMA had introduced in recent years to improve the effectiveness of its operations and made six recommendations dealing with:

- improved management of conflict of interest for advisory committees and service providers;
- improving reporting and transparency of registration timeframe performance;
- strategies for improving the quality of applications;
- the arrangements for receiving scientific advice from government agencies;
- improving the Manufacturers Licensing Scheme; and
- optimising the management of throughput and transparency within the Chemical Review Program.

The APVMA welcomed the report and is implementing each of the recommendations. The APVMA's implementation plan, which includes information on the progress of its implementation activities, is available from the APVMA website[41]. The APVMA believes that the performance audit has provided valuable recommendations for further improvements to its operations.

APVMA restructure

In early 2007 the APVMA commissioned an external review of the APVMA's organisational structure and resources. The aim of the review was to ensure that the APVMA's structure and resource allocations would allow the APVMA to perform effectively and efficiently following its

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40 The ANAO Performance Audit Report, *Regulation of Pesticides and Veterinary Medicines—Australian Pesticides and Veterinary Medicines Authority*, is available at http://www.anao.gov.au/uploads/documents/2006-07_Audit_Report_14.pdf.

41 The APVMA's ANAO audit implementation plan is available at http://www.apvma.gov.au/about_us/anao_report.shtml.

transition to executive management corporate governance arrangements on 1 July 2007[42]. The review also took into account the ANAO audit report and changing external contexts and expectations of the APVMA.

An outcome of this review has been the reform of the APVMA's structure and resource allocation to improve the effectiveness and efficiency of its operations. Three key themes to the new structure are a flattened management structure of the registration programs to allow increased resources to be directed towards timely and quality evaluation and processing of applications, a re-structure of the Programs so that one Program has a focus on strategic issues, reform, operational policy development and stakeholder engagement and a repositioning of a number of teams to Programs where natural synergies can be employed. Further information on the restructure is available via the APVMA website[43].

MRL alignment

For a number of years the APVMA has been involved in discussions with FSANZ and the Food Regulation Standing Committee (FRSC) to harmonise the MRL setting process. Recent amendments to the *Food Standards Australia New Zealand Act 1991* and a revised MOU with FSANZ are expected to reduce the lag between product registration and entry of the relevant MRL into the Food Standards Code. As noted in the FSANZ submission to the Commission, the reduction in time lag at this stage is expected to be from 9–12 months to 6–9 months for new chemicals and major extensions of use of existing chemicals. The APVMA acknowledges that these advances do not address all of the concerns of the chemicals and primary industries but remains confident that further reductions in time lag, encompassing MRLs for other application types such as permits, are possible. The APVMA welcomes the Commission's analysis of the matter.

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42 Further information on the recent changes to the APVMA's corporate governance arrangements is available from the APVMA website at http://www.apvma.gov.au/about_us/corpgov_arrangements.shtml#reforms.

43 Information on the APVMA corporate restructure is available at http://www.apvma.gov.au/new/hottopics.shtml#restructure.

8.2 PSIC policy and legislative reform activities

The APVMA is not directly involved in policy development, but plays an important role in informing the development of policy relating to the regulation of agvet chemicals. Policy development of the NRS is the responsibility of the Australian, state and territory governments as represented by PIMC. The APVMA contributes to the work of PSIC, a sub committee of PIMC.

PSIC is currently working on a number of reforms relevant to productivity in both the chemicals and plastics industry, and the primary industry. The key reform activities are discussed below.

Scope of Regulation project—improved definition of the types of products that are regulated as agricultural and veterinary chemicals

The APVMA regulates products if they fall within the definition of an agricultural or veterinary chemical product provided by sections 4 and 5 of the Agvet Code and by Regulations 7 and 8 of the *Agricultural and Veterinary Chemicals Code Regulations 1995* (the Agvet Code Regulations).

The APVMA agrees that some of these products would not commonly be thought of as agricultural chemical products (e.g. swimming pool products and personal insect repellents for humans) and may be better regulated through other mechanisms. The APVMA is the principal driver of a process though PSIC to review the scope of products captured by the NRS. To conduct the review PSIC has developed a decision-making framework to guide assessments as to whether specific chemical products should be included within, or excluded from the NRS, to determine the appropriate level of regulation and to identify the appropriate regulator for products that should continue to be regulated but by an authority other than the APVMA. The parameters of the decision-making framework are included in Appendix D.

These endeavours are expected to improve industry productivity by decreasing the regulatory burden without compromising public safety or the environment.

Improving efficiencies in the regulatory process for lower risk chemicals

In 2003 amendments to the Agvet Code provided for a low regulatory scheme for low risk product types. Under those provisions certain products or product types may be proposed by industry for listed registration or reservation. The APVMA will assess such proposals and determine their potential and feasibility and then make a proposal through PSIC to the Minister.

With regard to listed registration, during the consideration process a standard is determined and once approved new products may be registered with much reduced application requirements, provided they conform to the determined standard. Chemical products approved for reservation do not need to be registered with the APVMA provided that they are of a type described in the conditions of reservation and are only supplied for the purposes described in the conditions of reservation.

The APVMA recognised that the legislative framework for listed and reserved chemical products was not delivering the desired outcomes and recently proposed a revised system to PSIC within the existing legislative framework that will achieve results. PSIC has accepted the proposal and the APVMA is moving to implement it.

More efficient and transparent framework for higher risk chemicals in order for users to continue to have access to such chemicals

Acknowledging that the use of some higher-risk chemicals may need to be severely restricted or not allowed if sufficient controls are not in place, the Agvet Code provides for controls through declaring certain chemicals to be ‘restricted chemical products’ and imposing specific restrictions on their supply and use. PSIC with active participation by the APVMA is working on improving the framework for higher-risk chemicals. If the framework is not improved there is possibility that the uses of certain chemicals may need to be disallowed which may impair the productivity and competitiveness of certain primary industry sectors.

Minor Use Liaison Office

The APVMA acknowledges the difficulties of the ‘minor-use’ issue, which are also experienced internationally. Although additional to its core business, in 2004 the APVMA appointed a Minor-Use Co-ordinator to engage and provide a contact point for grower groups. It has also more recently contributed to a recent initiative in conjunction with DAFF of the Minor Use Liaison Office. This office was established in August 2006 with the objective to progress initiatives for minor uses and develop a long-term strategy for addressing minor use.

As mentioned previously, the APVMA chairs an OECD Expert Group on Minor Uses.

9 Opportunity areas for improvement

Considering the parameters of the current regulatory system as outlined in Section 5, *Current Regulatory Arrangements* and the significant reforms discussed in Section 8, *Current Reform Activities*, the APVMA believes that there are opportunities for improvement in the national governance of chemical regulation, the risk assessment and management of chemicals and in the area of regional uniformity.

9.1 Opportunity area 1: national governance of chemical regulation

As discussed in Section 5, *Current Regulatory Arrangements*, the current Australian Government chemicals regulation structural arrangements align the type and nature of regulatory assessment with use and exposure. These arrangements reflect the concept that the case for regulating is dependent on both hazard and risk with risk relating closely to the exposure potential commensurate with the intended use. However an intrinsic flaw in such arrangements is that they do not deal well with the interface between regulators in terms of the product types that lie near the borders of each regulator's responsibilities (the 'grey' areas), or those which due to their diverse usage fall into the regulatory field of more than one regulator. Figure 1 sets out products of this type. This poses a difficulty for the chemical industry as there may be regulatory overlap and the approach to dealing with such products may differ between regulators.

Currently there is no formal interactive relationship between the key regulators to:

- facilitate the refinement of their scope of regulation, particularly at the fringes of their regulatory responsibility (i.e. to identify the most appropriate regulator);
- align regulatory strategies for 'shared' products of similar risk; or
- streamline assessment processes.

Typically there is a need for flexibility around such interface issues and legislative solutions may not be optimal. As previously discussed, the national chemical policy departments and regulators currently interact through the Chemicals Clearing House, but this only has an international focus and does not provide a formal mechanism for regulation governance.

Figure 1 The product 'continuum' and interface between regulators

<table>
<tr><th>TGA</th><th>NICNAS</th><th>APVMA</th></tr>
<tr><td>Human Medicines →</td><td colspan="2">← Industrial Chemicals[44] →</td><td>← Agvet Chemicals</td></tr>
<tr><td colspan="2">Human cosmetics</td><td></td></tr>
<tr><td colspan="3">Disinfectants</td></tr>
<tr><td></td><td colspan="2">Biocides with commercial uses that may or may not have agricultural uses</td></tr>
<tr><td></td><td colspan="2">Biocides with domestic uses</td></tr>
<tr><td></td><td colspan="2">Consumer products</td></tr>
<tr><td></td><td colspan="2">Chemicals that become agvet chemicals because of claims</td></tr>
<tr><td>Sunscreen/Insect repellent</td><td rowspan="2"></td><td>Sunscreen/Insect repellent</td></tr>
<tr><td>Head lice treatment</td><td>Head lice repellent</td></tr>
</table>

To improve the efficiency of regulation and synergies between the key national chemical policy makers and regulators the APVMA believes that a formal cross-portfolio relationship is warranted with the authority to drive policy and if necessary legislative change within each of the respective portfolios. In order to be effective it is likely that such a structure would need to constitute a working group or subcommittee of the respective Ministerial Councils and comprise senior operational and policy personnel. The terms of reference could include key regulatory matters such as clarity over products that are regulated, increased adoption of international standards and the standardisation of assessment methodologies. It could also drive many of the initiatives that are likely to be put forward in this study.

Such an approach would improve regulatory consistency and more efficiently and effectively deal with product groups that because of their uses span across regulators by providing assurance that:

- product responsibility is adequately differentiated between regulators and that product groups that have multiple uses do not have duplicative regulatory requirements;
- assessment methodologies are consistently applied for risk areas that are managed for different uses;
- a whole of government consistent approach is applied to chemicals management, particularly in the area of emerging technologies (e.g. nanotechnology); and

[44] The definition of an 'industrial chemical' provided by the *Industrial Chemicals (Notification and Assessment) Act 1989* captures all chemicals with an industrial use whether or not they are also human medicines or agvet chemicals.

- through review, the legislation underpinning each regulator's responsibilities is consistent with risks posed and that legislation and policy applied in one area is considered for application to another area of regulation.

Proposal 1.0

That a formal interaction relationship be established to improve chemicals governance between chemical policy-makers and regulators (TGA, NICNAS, FSANZ and APVMA) in terms of the approach to chemicals regulation.

9.2 Opportunity area 2: risk assessment and management

The outcomes of the key national regulators and their "assessment products"[45] may vary, but the essential function of the outcomes is similar, in that standards are set. Given this similarity of function some have suggested that economies of scale may be achieved by merging regulators or regulatory functions. However this is not necessarily true. National regulators, such as TGA, NICNAS and APVMA, specialise in risk management within their respective industries.

Regulators must have a detailed understanding of the use industry in order to be relevant and effective. Increasingly, regulation is seen to be only part of chemicals risk management. For this reason regulators need to have an integral understanding of alternative mechanisms of risk management, including such tools as Quality Assurance Schemes and training programs used within the affected industries and be aware of trends in chemical application technologies including emerging technologies.

For example the APVMA as the regulator of chemicals for the agricultural sector of primary industry specialises in managing the risks identified in the hazard, exposure and risk assessments by applying the relevant assessment components to the particular circumstance of the chemical user in that sector. The APVMA's evaluation staff have particular expertise in this sector. Their expertise differs from that necessary to appropriately apply risk management to the use of chemicals in other sectors. Such expertise is of particular importance to facilitate regulatory responsiveness to industry needs and developments while ensuring that regulatory outcomes are appropriate and effective in satisfying the needs of the broader community to protect public health and the environment.

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[45] Assessment products are the outcomes of an assessment process and may include a report, a registration, a licence or a standard.

The continued regulation of chemicals by government departments or authorities with expertise in their use ensures that the use industries continue to be supported by relevant and effective regulation. Indeed the APVMA's mission is 'to protect the health and safety of people, animals and crops, the environment, and trade, *and support Australian primary industries* [emphasis added] through evidence-based, effective and efficient regulation of pesticides and veterinary medicines'.

Proposal 2.1

That chemicals continue to be regulated by agencies with expertise in their use (i.e. agvet, industrial, human medicines).

Alternately the greatest opportunities for improved efficiencies and consistency of chemical risk assessments may lie in ensuring that the methods for assessing hazards and risks are consistent between the key regulators and their assessing departments or agencies. As previously outlined, government's fundamental role in regulatory risk assessment is in standard setting. The assessment of hazard and risk with respect to matters such as toxicology and public health, OH&S and environment require highly specialised experts and are assessment components common to multiple regulators.

Considering that the standards are determined for the public good, it is reasonable that these standards and the methodologies by which they are assessed or determined, should be nationally consistent and that their determination be centralised into single specialist agencies within the relevant responsible portfolios[46] to ensure that the advice on which regulatory decisions are made is nationally consistent. As depicted in Table 1, some components of national exposure and risk assessment are currently quite dispersed.

The conduct of similar hazard and risk assessments for the same assessment component[47] by a number of groups or agencies creates opportunities for the encroachment of differing cultures or approaches to the application of policy and the potential for differing assessment methodologies. This in turn may increase the potential for inconsistencies in assessment outcomes unless managed by appropriate governance arrangements. It also disperses specialist staff, decreases flexibility and

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[46] For example, DoHA has responsibility for public health standards and DEW has responsibility for environmental standards.

[47] The hazard and exposure assessment components of relevance to each of the key regulators (TGA, APVMA, NICNAS and FSANZ) are listed in Table 1.

potentially increases administrative costs, particularly in terms of information sharing and national and international participation and representation.

The centralisation or consolidation of specialist advice providers would work to improve consistency in methodologies of assessment as well as the determination and acceptance of acceptable thresholds and improve the consistency of the advice on which regulatory decisions are made. Improved centralisation of specialist advice providers may facilitate alternate methods of approaching the assessment of chemicals. For example it may be possible for chemical proponents or sponsors to seek certain assessments such as for toxicology and environment prior to making application to the regulator. This would transfer the administrative burden and cost of organising and managing those assessments from the regulator to the applicant, with an associated reduction in the regulator's assessment fees and timeframes. Such an option may be attractive to some members of the chemical industry.

Proposal 2.2

That economies of scale and consistency be achieved by centralising specialist advice providers such as those for toxicology, OH&S and environment in the relevant portfolios, so that all regulators get their advice from the same agencies.

Furthermore, the spread of assessment service providers for the same assessment component increases the difficulty of developing a whole of government standardised position on the specific aspects of the assessment process that is essential government work (e.g. the setting of national standards). It also clouds those aspects that could be outsourced to other service providers thereby introducing contestability and creating competitive pressures on costs and timeframes.

An ANAO audit of the APVMA in 1997–98 and the recent 2006 ANAO Performance Audit of the APVMA (discussed in Section 8, *Current Regulatory Reform Activities*) have challenged the existing arrangements for the provision of advice from other government departments to the APVMA and have suggested the use of alternative sources of advice. To this end a Parliamentary Secretary agreement to an outsourcing process for provision of certain aspects of hazard and exposure assessments has been implemented. The APVMA is currently working with other government departments on the development of formal Ministerial agreements to clarify the role of government in the assessment process and to identify areas for greater flexibility in service provision. This is expected to provide productivity gains for the chemicals industry by improving the cost and time structures of assessment advice given to the APVMA.

Additional efficiencies to chemical risk assessment activities may be realised through the continued improvement and facilitation of international linkages. As discussed in Section 6, *International Linkages*, the APVMA actively engages with its overseas counterparts to facilitate improved efficiencies wherever possible and practicable. The APVMA strongly supports the acceptance of relevant international standards and dossiers where practicable. With respect to agvet chemicals, due to the climatic and agronomic uniqueness of Australia and the often unique Australian chemical use patterns, the greatest opportunities for alignment in terms of 'portability' of data and hazard and risk assessments lie in the human and environmental toxicology risk assessment components. The APVMA's ability to realise such opportunities is however somewhat dependent on the willingness of its specialist advice providers to accept international dossiers and hazard assessments conducted by competent overseas authorities. Australia's and the APVMA's continued participation in international forums is important to facilitate the adoption of acceptable, uniform and consistent standards in both Australia and other similar developed nations.

Proposal 2.3

That regulators continue to facilitate international linkages and encourage the adoption of international standards.

In conjunction with the potential efficiency improvements outlined above, the APVMA acknowledges that that the regulatory environment is dynamic and that regulators must continually look to refine and improve processes and adapt to the needs of their stakeholders within the bounds of their mission. As discussed in Section 8, *Current Regulatory Reform Activities*, the APVMA has been highly proactive in developing initiatives and reforms to create efficiencies in the delivery of its outputs. As outlined in the APVMA Corporate Plan, innovation is a key organisational value, adopting innovative ways to continue to improve our efficiency and effectiveness.

Proposal 2.4

That regulators continue to innovate and introduce operational reforms in collaboration with the chemical industry to improve the efficiencies of service delivery.

9.3 Opportunity area 3: regional uniformity

As discussed in Section 5, *Current Regulatory Arrangements*, the outcomes or assessment products of the national regulatory bodies are applied or adopted by the states and territories via three key avenues. Variability in adoption has the potential to impact on the effectiveness of regulation as the assessment conducted at the national level (such as in terms of risk to public health and environment) is generally on the basis of the application of the standard as a whole, rather than in part. In the case of agvet chemicals, the focus of the APVMA assessment is in terms of use according to label instructions. The safety aspects of usage outside those instructions are often unknown as they have not been the subject of assessment of use according to label instructions.

The APVMA notes that consistency in the enforcement of regulation between the various jurisdictions was raised in a number of submissions to the Annual Review of Regulatory Burdens on Business and has been raised in the Issues Paper to this study as a potential impediment to productivity. This issue was acknowledged as a challenge in the 2002 Allen Report. As previously discussed, with respect to agvet chemicals, improved efficiencies are intended through the adoption of national operating principles. This approach may also be enhanced through formal or consistent mechanisms of intra-state coordination, such as that provided by the Pesticides Advisory Committee in Western Australia.

As acknowledged in the Issues Paper, the development of integrated and nationally coordinated systems is complex, with jurisdictions needing to balance a desire for cooperative federalism with local preference. In order to fully achieve a seamless and nationally consistent regulatory and chemicals management framework that encompasses all aspects of chemicals management, other methods of rationalising Australian Government, state and territory roles may be required.

Proposal 3.0

That the standards set at the Australian Government level be adopted uniformly in states and territories by either the states or territories adopting national operating principles or by the Australian Government undertaking compliance activities.

The uniform adoption and enforcement of standards from a national perspective (a nationally consistent seamless system) will offer surety for chemical and user industries and facilitate efficiencies in the delivery of regulation.

10 Conclusion

The APVMA is committed to improving its regulatory efficiency and assisting the Australian Government's objective to minimise 'red tape' without compromising the overall policy objective of the NRS.

The APVMA services a diverse range of stakeholders which reflects the diversity of its regulatory operating environment. Previous reviews have highlighted the dynamic nature of agvet chemical regulation and the need for ongoing reform and continuous improvement to standardise and achieve efficiencies in the delivery of regulatory objectives.

The APVMA recognises there are areas in which improvements can be made to not only improve the efficiency of regulation but also the effectiveness of regulation in achieving policy objectives. The APVMA has been highly proactive in developing and delivering operational reforms and has continued to work with policy makers to further improve and refine the NRS to align it with contemporary needs and demands. In addition, the APVMA has worked to develop and take advantage of international linkages to produce efficiencies in the delivery of its regulatory functions where possible.

Notwithstanding the efficiencies and reductions to regulatory burdens that have and will continue to arise from these reform activities, many of which are ongoing, the APVMA believes that there are a number of opportunities to achieve further improvements in the efficiency and effectiveness of chemicals regulation. In particular, these opportunities lie in the areas of national uniformity of risk assessment and enforcement and in the improved coordination and synchronization between the key national regulatory bodies.

Acknowledging that all regulation has a cost and that the focus of this study is to identify avenues to reduce unnecessary costs or regulatory burdens (i.e. those which are over and above the necessary costs inherent in meeting policy objectives), the APVMA strongly supports research in the area of quantitative cost effects of regulation. Objective data detailing the extent of the cost burden that regulation imposes appears to be lacking. If such data were available, it would better inform governments on the actual, as distinct from the perceived, cost effects of regulation (and particular the additional costs arising from regulatory duplication or redundant regulation). Given the diverse perceptions between stakeholders in relation to the excessive nature of regulatory burdens such information would assist governments to refine the positioning of regulatory systems.

The APVMA looks forward to further discussing matters relating to the regulation of agvet chemicals with the Commission.

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Appendix A: APVMA functions and activities

The APVMA conducts a number of key functions, including:

Registration and approvals

- assessment of applications related to active constituents, chemical products and labels
- approval of active constituents, chemical products and labels
- assessment of applications for permits to authorise the otherwise illegal supply and use of chemical products
- issue of permits, including those for minor use and experimental use.

Specialist assessment services

- residues assessment
- chemistry assessment.

Chemical Review

- review (reconsideration) of existing chemical products including data call-in, assessment, finalisation and associated compliance activity.

Adverse Experience monitoring

- assessing Adverse Experience Reports and taking further action where warranted.

Manufacturers Licensing Scheme

- conducting a Manufacturers Licensing Scheme including the assessment of applications, the issue of licences and auditing.

Compliance

- ensuring industry compliance with legislation and registration conditions including advising/warning, conducting recalls, monitoring visits, briefs for prosecutions and product testing, monitoring of hormonal growth promotants (HGPs).

Other

- informing policy
- international participation including standard setting (e.g. OECD and CODEX).

Appendix B: adoption of international standards

Recommendation 4.56 of the Banks Report proposed that any uniquely Australian variation of international standards or agreements relating to regulations in the chemicals and plastics sector must be contingent on a demonstration of net public benefit. To inform the discussion on the use of international standards, data and assessments and to facilitate a comprehensive analysis of the how best to leverage international linkages, it is useful to outline the scope of the topic.

Broadly speaking, the term 'international standards and agreements' includes:

Data requirements (including guidelines and information requirements)

- *Harmonisation of data requirements via harmonised guideline development*

  The government can facilitate the introduction of international products if registrants use a data package generated overseas for a registration application in Australia.

  Example: the APVMA is involved with development and then implements VICH guidelines and OECD guidelines on data requirements.

- *Adoption of international regulatory guidelines*

  The government can facilitate the introduction of international products if registrants use a data package generated overseas for a registration application in Australia. This also allows a regulator such as the APVMA to provide better information to applicants if guidelines developed overseas suit our purposes without revision.

  Example: APVMA could adopt the European Agency for the Evaluation of Medicinal Products (EMEA) Guideline on Statistical Principles for Veterinary Clinical Trials.

Submission formats

- *Harmonisation of formats*

  The government would accept submissions formatted in an international format.

  Example: the APVMA currently accepts and encourages applicants to use OECD submission formats for data dossiers.

- *Development of e-submissions to facilitate reporting*

  The government would accept submissions electronically, rather than in paper form.

  Example: the APVMA is currently accepting some applications for registration on-line (non-technical), will accept submissions on CD-ROM in addition to requesting a hard copy and is working to introduce fully electronic applications in 2008.

Risk assessment methodology on either specific risk areas or product groups

- *Harmonisation of risk assessment methodology*

  The government may facilitate the introduction of international products if registrants, using a data package generated overseas for a registration application in Australia, can predict that a similar regulatory decision will be reached by the APVMA because assessment methodology is similar.

  Example: APVMA is currently conducting work considering the alignment of assessment methodology with New Zealand regulators.

Risk assessment reports on specific risk areas

- *Consideration of overseas regulatory assessment reports on specific risk areas, in lieu of Australian assessment*

  The costs associated with the introduction of a new product to Australia are reduced as time (and costs) spent in assessing data that has already been assessed to a suitable standard by an international regulator is reduced.

  Example: the Australian Government could accept a Canadian risk assessment of the toxicology of a new pesticide.

Combined risk assessment reports for specific products (covering all risk areas)

- *Consideration of overseas regulatory assessment reports for specific products, in lieu of Australian assessment*

  The costs associated with the introduction of a new product to Australia are reduced as time (and costs) spent in assessing data that has already been assessed to a suitable standard by an international regulator is reduced.

  Example: APVMA could accept the total risk assessment of a new companion animal veterinary medicine that has been assessed by the US FDA.

Regulatory decisions/risk management (product registration or label approval or GMP licensing, standards/regulatory limits)

- *Adoption of regulatory decisions without further assessment*

  The costs associated with the introduction of a new product to Australia are reduced as time (and costs) spent in assessing data that has already been assessed to a suitable standard by an international regulator is reduced.

  Example: the APVMA currently accepts GMP licences issued by European Union and New Zealand authorities.

- *Adoption of standards without further assessment*

  The Australian Government could avoid unnecessary repeating of work already done by a reputable overseas body.

Example: Australia could accept relevant CODEX MRLs or FAO pesticide specifications without further assessment.

Publication of regulatory assessments using international formats

- *Harmonisation of format*

  Government reports would be in a consistent format to international reports.

  Example: under current work-share arrangements the APVMA is using OECD formats for reports.

Appendix C: timeframes for evaluation of applications for registration or applications for permits

Background

Schedules 6 and 7 of the Agvet Code Regulations prescribe fees for different categories of applications for registration of a new product or a variation to the registration of an existing product. The Regulations also prescribe the maximum timeframes within which an application must be finalised.

The timeframes range from three months (a fee of $540) for a simple variation to an existing product to 15 months (a fee of $48,860) for a new product containing a new active ingredient.

APVMA timeframes and costs compare favourably with those of our overseas counterparts. For example, the US Environmental Protection Agency equivalent of the 15-month category takes between 24 and 36 months and costs US$475,000.

The timeframes are measured in ‘clock time’, not calendar time. If an application cannot be progressed because the applicant must provide supplementary data, the clock is stopped until the data is provided. For this reason, an application that may have a prescribed timeframe of five months may require 12 calendar months (or more) to finalise.

Statutory timeframe and timeframe performance

Schedules 6 and 7 of the Agvet Code Regulations provide timeframes within which the APVMA must determine (finalise) applications. The APVMA refers to these schedules as the statutory timeframes.

Section 165 of the Agvet Code requires the APVMA to finalise an application within the statutory timeframe. However Section 165 also provides that in calculating the period within which the application is to be determined (the statutory timeframe) no regard is to be had to, amongst other things, any period beginning on the day when the APVMA makes a requirement of the applicant in connection with the application and ending on the day when the requirement is complied with. As previously discussed, as an outcome of its 2006 Performance Audit of the APVMA, the ANAO noted that 74 per cent of pesticide and 76 per cent of veterinary medicine applications made to the APVMA contained errors (deficiencies).

Statutory timeframe and elapsed time

The statutory timeframe for the assessment of applications is the time period set out in Schedules 6 and 7 of the Agvet Code Regulations. Elapsed time is the total time between the APVMA accepting the application for evaluation (i.e. having passed screening) and issuing of the notice of registration or approval or variation. Elapsed time includes all the time it takes the APVMA to assess the application plus the time it takes for the applicant to respond to any APVMA requests for:

- clarification of the application
- submission of extra data
- amend label claims or directions
- submit marketed product labels (MPLs) for approval

To the APVMA, elapsed time is the time between the APVMA passing the application to evaluation after screening, and issuing the notice of registration or approval or variation.

To an applicant, elapsed time includes the time between posting the application to the APVMA and receiving the notice of registration or approval or variation. Therefore, to an applicant, elapsed time includes the time the application and notice are in the postal system and also the time the application is in screening.

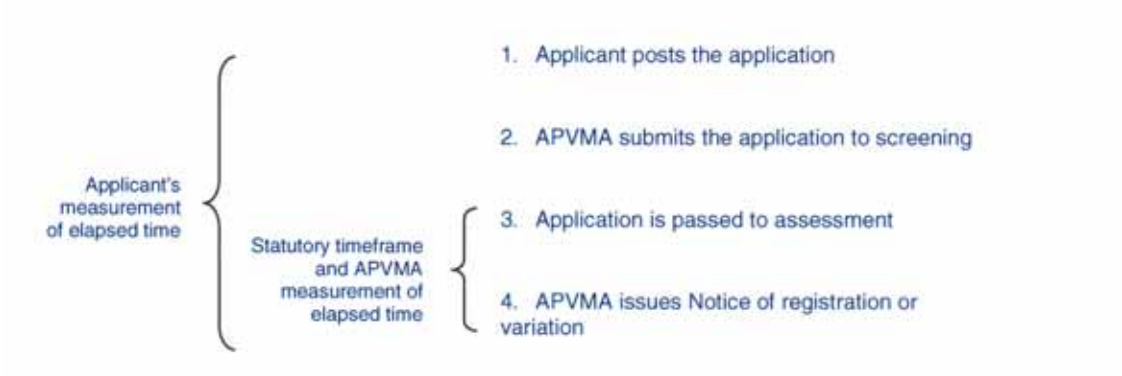
The APVMA does not include the time the application is in screening in its calculation of elapsed time because the effect of sections 11 and 11A of the Agvet Code is that an application is not properly made until it passes screening.

Elapsed time is of fundamental importance to an applicant because:

- it feeds into marketing plans (e.g. product launch dates to coincide with seasonal conditions or an industry conference)
- it determines when the applicant may sell the product and receive a revenue stream.

Statutory time and elapsed time are shown in Figure C1.

Figure C1 Statutory timeframes and elapsed time



Measurement of statutory timeframes and elapsed time

Table C1 shows average annual data for agricultural and veterinary applications for the past four financial years. The data show that the average elapsed time taken to finalise applications is two to five times the average statutory time.

Table C1 Average annual statutory time and elapsed time to finalise agricultural and veterinary applications for the past four financial years

Agricultural applications								
Target Statutory Timeframe	2003/4		2004/5		2005/6		2006/7	
	ST	ET	ST	ET	ST	ET	ST	ET
2–3 months	1.7	5.9	1.7	7.1	1.5	5.9	1.2	5.1
5 months	5.4	16.5	5.8	17.2	5.2	13.3	5.4	12.5
6–8 months	7.7	21.7	8.2	21.3	9.1	19.7	8.4	15.4
9–12 months	8.6	32.0	13.8	27.1	10.9	26.1	12.8	36.0
13–15 months	12.2	21.2	12.5	25.2	14.3	31.6	11.8	30.9

Veterinary applications								
Target Statutory Timeframe	2003/4		2004/5		2005/6		2006/7	
	ST	ET	ST	ET	ST	ET	ST	ET
2–3 months	1.2	7.7	1.3	6.5	1.3	5.9	0.7	5.1
5 months	2.9	9.6	3.4	10.4	3.4	10.4	4.2	11.5
6–8 months	5.2	16.0	5.8	19.8	4.5	20.1	5.5	18.6
9–12 months	12.1	15.5	9.1	54.0	11.6	19.9	-	-
13–15 months	5.6	27.2	8.4	22.9	8.6	21.3	5.9	26.2

Note: ST = actual statutory time in months; ET = actual elapsed time in months.

Appendix D: National Registration Scheme (APVMA) scope of regulation decision-making framework.

The NRS regulates products that meet the definition of an agricultural or veterinary chemical product under Sections 4 and 5 of the Agvet Code. At the time the NRS was established, these definitions were made broad enough to capture most products that were previously registered under individual state or territory schemes. In recognition that such broad definitions could capture products at the margins and to provide clarity, a list of products were declared to be or not to be agvet chemical products by the Agvet Code Regulations.

Since the establishment of the NRS, the regulatory environment has evolved, challenging the definition of agvet chemicals. The APVMA responded by proposing to review the scope of products captured by the NRS. PSIC agreed and has developed a framework for assessing chemical products (see below) to decide whether a product which falls within the scope of the NRS should be regulated and, if so, whether it should be regulated by the APVMA or another agency, and further if it should be regulated, the method by which it should be regulated.

Assessment framework questions

Determine whether the product falls within the scope of the National Registration Scheme

- Does the product fall within the current definition of an agricultural or veterinary chemical product?
- Has a policy decision been made to include or exclude the product within the scope of the NRS?

Determine whether the product should be regulated

- What are the common active constituents of the chemical product?
- What kinds of risks are associated with the use of this chemical product?
- What is the potential risk of using the chemical product?
- What risk management strategies are needed for this chemical product?
- Is regulation needed to deliver the risk management strategies?

Determine which agency should be the regulator

- If regulation is needed, which regulator is best placed to deliver the risk management strategies?

- If another agency is the appropriate regulator, has it agreed to accept responsibility for regulating the product?

Determine how the product should be regulated

- If the APVMA is the appropriate regulatory agency, how can these strategies be delivered?
- Other considerations (e.g. are there other similar products or new uses that could be managed in the same way?)

PSIC has applied the above framework to a range of product types and classes currently captured by the agvet chemical definitions and are actively working to apply the assessment outcomes.