BETTER REGULATION OF AGRICULTURAL AND VETERINARY CHEMICALS

REGULATION IMPACT STATEMENT

NOVEMBER 2011

Contents

Section 1 Introduction

This regulation impact statement (RIS) deals with the Commonwealth's regulation of agricultural chemicals and veterinary medicines ('agvet' chemicals).

Agricultural chemicals (also known as pesticides) include a wide range of products for the control of weeds, insects and fungal pathogens and are widely used in agricultural and forestry industries to ensure pest control is effective and the industries are productive. In other contexts pesticides are important in the protection of buildings, parks and infrastructure. They are also used in households for the control of a range of pests. Pesticides have a role to play in protecting the environment from pests such as locusts, foxes and weeds. They are used in human health for protecting against disease vectors such as mosquitoes. Equally, veterinary medicines, such as vaccines, antibiotics, anthelmintics (e.g. worm treatments), ectoparasiticides (e.g. lice treatments) and some vitamins and minerals, are important to protect livestock—an integral part of Australia's primary industries sector— from pests and to treat a wide range of diseases and illnesses. These products are also essential for maintaining the health and wellbeing of companion animals, including domestic pets.

Access to and use of agvet chemicals is regulated through a two-tiered system, the National Registration Scheme (NRS)[1]. The NRS is a partnership between the Commonwealth and the states and territories, with a shared division of responsibilities. Assessment and registration of agvet chemicals, as well as control of supply activities up to the point of retail sale is undertaken by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Control of use of agvet chemicals after sale is the responsibility of individual states and territories.

The APVMA is an Australian Government statutory authority within the portfolio of the Minister for Agriculture, Fisheries and Forestry, and has responsibilities under the *Financial Management and Accountability Act 1997* (FMA Act) and the *Commonwealth Authorities and Companies Act 1997* (CAC Act). The Chief Executive Officer (CEO) of the APVMA is responsible for the management and governance of the authority and reports directly to the Minister. The CEO is supported by an advisory board, two principal scientists, visiting fellows, five senior executives and 140–150 staff.

With input from relevant Commonwealth government agencies the APVMA approves active constituents and agvet products, undertakes reviews of existing approvals and registrations and monitors the compliance of approvals and registration up to and including the point of retail sale. The APVMA's assessment process provides assurance, through rigorous science based risk assessments, that agvet products are safe for human health and the environment. It also provides assurance that agvet products will be effective and will not adversely affect Australia's ability to trade agricultural produce. Australia currently has around 9900 separate agvet chemical products registered, each of which contains one or more of around 1883 approved active constituents, of which 779 are unique.

1 The NRS was agreed on by the Australian Agriculture Council (now the Primary Industries Ministerial Council) in 1991 and is described in a ministerial level intergovernmental agreement that was signed in September 1995.

1.1 Context of the reform proposal

The Australian Government has committed to reforms to the registration and review of agvet chemicals that improve the efficiency and effectiveness of the current regulatory arrangements and provide better protection for human health and the environment. The Better Regulation Ministerial Partnership (the partnership) between the Minister for Agriculture, Fisheries and Forestry and the Minister Assisting on Deregulation has, following extensive stakeholder consultation from mid-November 2010 through to early February 2011, identified a range of potential reforms. The reforms aim to cut unnecessary red tape for business and encourage the development of cleaner and safer chemicals. The reforms also aim to reduce the backlog of chemicals requiring review and remove the disincentive for companies to invest in cutting edge technologies.

In parallel with the partnership, the Council of Australian Governments (COAG) has identified chemicals and plastics as a regulatory 'hot spot' and it is seeking reforms to reduce the regulatory burden on business. COAG directed the Primary Industries Ministerial Council (PIMC) to bring forward a proposal for a single, national framework to improve the efficiency and effectiveness of the regulation of agvet chemicals. This is currently being developed. This process is being guided by policy principles that were agreed on by COAG in August 2010.

1.2 Roles and responsibilities of the APVMA

The APVMA is responsible for the regulation of agvet chemicals to ensure the protection of the health and safety of people, animals and crops, the environment, and trade. It does this through:

- evidence-based evaluation and approval of active constituents and the registration of agvet chemical products
- the review of certain agvet chemicals of concern to ensure that they continue to meet contemporary standards, and
- monitoring, compliance and enforcement.

The APVMA's regulatory functions are defined by the:

- *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Admin Act), which established the APVMA; and
- *Agricultural and Veterinary Chemicals Code Act 1994*, together with its schedule (the Agvet Code) which provides detailed operational procedures on the registration and management of agvet chemicals.

The APVMA is responsible for administering and managing the parts of the NRS that oversee registration, quality assurance and compliance of agvet chemicals up to and including the point of retail sale. The responsibility for the control of use of agvet chemicals rests with the individual states and territories.

1.2.1 Approval of active constituents and agvet chemical registration

Agvet chemical products are often complex mixtures of the active constituent(s), solvents, diluents, stabilisers and other substances.

Active constituents are the substances within agvet chemical products that are primarily responsible for the biological or therapeutic effect of the product. Active constituents are usually approved separately to the product either before or at the same time as the product is being registered. During the approval of an active constituent the APVMA undertakes an assessment to determine whether it can be satisfied that the use of that active constituent in a product will not have a harmful effect on human health, the environment, occupational health and safety, or trade. The primary reason for the separate active constituent approval is to ensure that active constituents comply with an appropriate standard and do not contain unacceptable levels of potentially harmful impurities. If satisfied, the APVMA will approve the active constituent.

The process for the registration of agvet products is similar to that for the approval of an active constituent; however, the focus of the assessment is on the product and its use. The assessment determines whether the agvet product, when used in accordance with the label directions, would have a harmful effect on human health, the environment, occupational health and safety, or trade. Assessments can be complex and lengthy (some may take up to 15 months to complete) and will take into account a wide range of scientific data and information. Other applications—seeking a variation to an existing registration—may be less complex and are completed in three to 13 months depending on the change being made and the amount of data that needs to be assessed. In its assessments the APVMA routinely seeks the advice of other Commonwealth government agencies (its regulatory partners) such as the Office of Chemical Safety and Environmental Health (OCSEH) within the Department of Health and Ageing and the Department of Sustainability, Environment, Population and Communities (SEWPaC) and relevant state and territory departments[2]. It is on the basis of this advice that the APVMA decides either to grant the application where is satisfied that the product meets the statutory criteria for registration or to refuse the application where it is not. If registered, the agvet product may then be legally sold and used in Australia.

In most states, agvet products must be used only for the purposes that are specified on the product label. Their use in other situations would, in many cases, be regarded as illegal. To authorise the temporary use of an agvet chemical in specific situations for which they are not registered, the APVMA may issue a permit, subject to the application being able to meet certain statutory tests that apply to product registration. Situations for which the APVMA may issue a permit include research purposes, emergency use and use in minor crop situations where there are no registered alternatives.

1.2.2 Chemical review

The chemical review program reconsiders the approval and/or registration of agvet chemicals in cases where potentially unacceptable risks to human health, worker safety, the environment, trade and/or product performance have been identified. A reconsideration (commonly called a chemical review) may be initiated when new

[2] The APVMA's regulatory partners provide services to the APVMA, including hazard characterisation and standard setting for health and the environment.

research or information (such as a pattern of adverse experiences) has raised concerns about the use or safety of a particular chemical or product.

Reviews may be based on one, several or all risk areas and may be conducted on a single product or multiple products. The review process draws on specialist advice from within the APVMA and from its regulatory partners and includes extensive consultation with the chemical industry, users, the community and the states and territories.

Depending on the review's findings, active constituents and the products containing them might:

- be confirmed as safe and appropriate for registered use
- be restricted in use, including by making label amendments to limit the situations in which product/s may be used, or
- have its registration suspended pending specific action or cancelled or be withdrawn voluntarily from the market.

The APVMA reviews active constituents and agvet chemicals as resources permit, according to an established review priority list. Priority is given to agvet chemicals that have given rise to the greatest concern. The APVMA can call on the public to nominate agvet chemicals for review. At 31 March 2011 28 active constituents or chemical groups are under review. A further 40 active constituents were prioritised for review, including 11 high-priority nominations.

1.2.3 Compliance and enforcement

Compliance action involves the assessment of risk and the application of appropriate enforcement responses to breaches of the Agvet Code. The standards set in the registration process are enforced in the marketplace using a range of compliance strategies applied at the relevant points in the supply chain. The APVMA employs three distinct strategies to ensure that products comply with the Agvet Code. They are:

- prevention—aimed at promoting greater awareness and understanding of registration and compliance requirements
- quality facilitation—achieved through the publication of a wide range of standards and guidelines, such as the registration guidelines, the product labelling code and product recall guidelines. The APVMA has also implemented the Manufacturers Licensing Scheme to license all manufacturers of veterinary chemical products in an effort to achieve high standards of quality and facilitate exports, and the Adverse Experience Reporting Program to record and monitor any adverse experiences resulting from the use of agvet chemicals
- monitoring and enforcement—the APVMA actively investigates alleged breaches and implements risk-based enforcement strategies, such as recalls, warnings and injunctions.

Section 2 The problems

While the APVMA's regulation of agvet chemicals is effective in protecting human health and safety; the environment and Australia's ability to trade its agricultural produce internationally, the Australian Government recognises that the system is not working as efficiently and effectively as it should.

The need for improvements in the authority's efficiency and effectiveness is demonstrated by performance data that showed that during the 2009–10 financial year about 12 per cent[3] of applications for veterinary medicines and about 18 per cent[4] of applications for pesticides were not finalised within the statutory time frame. The duration of chemical reviews—on average 5 years and 8 months[5]—and the low number of regulatory decisions taken by the APVMA in relation to chemical reviews provide further evidence of the need to improve its efficiency and effectiveness.

While many factors have contributed to the inefficiencies within the APVMA and have limited the effectiveness of its operations, those described below are presented as they relate to its three core activities. The absence of a transparent and published risk framework is also recognised as a significant factor contributing to the problems identified in the three core areas, and this has therefore been presented separately. Issues relating to the use of international data and data protection arrangements are also common to one or more of the APVMA's core activities.

2.1 Risk framework

Although the responsibilities of the APVMA are clearly established in the Agvet Code, the APVMA has some flexibility in its approach to agvet chemical regulation, including its approach to the assessment and management of risk. To an extent, this flexibility enables the APVMA to align application requirements with the level of risk an application is expected to present. Likewise, with chemical reviews, the APVMA can target the issues of concern, rather than comprehensively review all aspects of the registration where no risk has been identified. The current compliance regime provides limited options to respond to issues of non-compliance.

To date, the APVMA has not clearly articulated its approach to the assessment and management of risk in a risk framework. This is also true for the APVMA's regulatory partner, OCSEH. While SEWPaC has developed elements of a risk framework related to its environmental impact assessments, these have not been integrated in a broader risk framework. The absence of a complete risk framework, combined with the flexibility the Agvet Code currently provides, creates uncertainty for stakeholders, and has been identified as having a major impact on the efficiency and effectiveness of agvet chemical regulation.

Some community and environmental stakeholders have expressed concern about the absence of a transparent risk framework for the assessment and review of agvet chemicals. This lack of transparency limits their ability to understand how regulatory decisions are made and can limit the extent to which they can participate meaningfully in

[3] http://www.apvma.gov.au/about/reporting/docs/vet_2009-10.pdf
[4] http://www.apvma.gov.au/about/reporting/docs/ag_2009-10.pdf
[5] ANAO Audit Report No 14, 2006–07, Regulation of Pesticides and Veterinary Medicines.

public consultation. The absence of a risk framework has the potential to undermine public confidence in the NRS and its ability to protect public health and the environment.

There are currently 950 agvet chemical registrants and approval holders interacting with the APVMA[6]. Each is in the position of having to make applications to the APVMA without a complete understanding of its approach to assessing risk. This affects their ability to make applications that address the APVMA requirements and that will proceed through the assessment process efficiently. This in turn can result in lengthy delays during the registration process and introduce additional costs. The potential for delays adds uncertainty, which in turn affects businesses' ability to plan production and marketing. Agvet chemical registrants and approval holders have also raised concerns that the APVMA's decision-making process is variable and outcomes cannot be predicted with any certainty. This lack of transparency and consistency acts as a disincentive for investment in agvet chemical development and registration in Australia, and has been identified as a possible reason why agvet chemicals registered overseas are not registered in Australia. This affects agvet chemical users, especially primary producers, who do not have access to the same range of pest control and animal health options that their overseas competitors do.

Limited ability within the existing regulatory framework to match regulatory effort with risk means that the APVMA operates in a way that can result in unnecessary costs to business and limit opportunities for innovation through registration of new agvet chemicals. Applications must be assessed against all parts of subsection 14(3) of the Agvet Code, which describes what the APVMA must consider in deciding to grant or refuse an application, irrespective of the risk that the product poses. For example, applicants must demonstrate the efficacy of their product, but the code does not allow the APVMA to consider the risk associated with excluding that element from its consideration. This may impose unnecessary data requirements on applicants. These requirements, then, have the potential to influence an applicant's decision to make an application. One stakeholder cited, in confidence, the examples of kairomones (for example, a flower scent used to attract or repel other species) and pheromones, which are registered for use as pest control products in the United States but the companies involved have decided that the cost of seeking registration in Australia makes this uneconomic. A key reason for this decision was the APVMA's requirements for data that were not required by regulators overseas. As well as increasing the cost to business, these requirements limit the range of agvet chemicals, including new and innovative products, available to users.

Without a clear risk framework the APVMA also has reduced capacity to apply a proportional response to non-compliance. A more targeted approach in this area would make more efficient use of the APVMA's resources, to the benefit of the regulated community. A clear risk framework would also enable the APVMA to demonstrate that the action taken to address issues of non-compliance is focused on those that pose the greatest risk and that the response is proportional. More effective compliance action would benefit the broader community, as well as members of the regulated community who comply with the relevant regulations, through improved consumer confidence in the regulatory system.

[6] There are currently 855 individual product registrants and 268 individual constituent approval holders. There are 174 companies that hold both product registrations and active constituent approvals (APVMA, pers comm., March 2011).

Additionally, stakeholders have raised concerns about the extent to which the APVMA takes international data and assessments into account in the course of its assessment. In the absence of a framework for considering such data, there is a tendency for individual expert evaluators to conduct a 'from the ground up' detailed peer review of the overseas hazard assessment (which is generally applicable) rather than focusing on the risk assessment, standard setting and risk management component (which are more specific to Australian conditions).

2.2 Registrations and approvals

2.2.1 Lodging applications

Stakeholders have criticised the current preliminary assessment phase, suggesting that it is inefficient and is used by the APVMA to consider aspects of the application that should be assessed during the full evaluation once the application has been accepted.

Existing legislation allows the APVMA to defer, treat as withdrawn or reject an application during the preliminary assessment phase if it does not include all the relevant information for assessment and the APVMA considers that the application cannot be reasonably rectified. In each of these circumstances the Agvet Code provides the APVMA with considerable discretion to determine the circumstances in which it should reject an application.

APVMA figures for a six-month period in 2010 (for a limited number of application categories) show that deficiencies were identified with 11 per cent of veterinary medicine applications and 23 per cent of pesticide applications at the administrative screening phase. During technical screening (as part of the preliminary assessment) deficiencies were identified with 39 per cent of veterinary medicine applications and 31 per cent of pesticide applications. More than 30 per cent of all applications contained more than one deficiency at either stage. The figures also show that 23 per cent of all technical screening deficiencies related to the use of an incorrect category, such as those relating to closely similar products. In relation to category 7 for pesticides, this was significantly higher at 31 per cent. This is significant because there is often an incentive, in terms of time, money and data requirements, for an applicant to make an application in category 7 in the hope that it will be accepted.

In 2009–10 no applications were rejected in the preliminary assessment phase; however, 101 applications for veterinary medicines and 213 applications for pesticides were withdrawn by the applicant or treated by the APVMA[7] as having been withdrawn.

Clearly, this process places an administrative burden on the APVMA, and results in a diversion of resources from those applications that have progressed to the full evaluation stage, potentially adversely affecting the timeliness of their assessment.

2.2.2 Assessing applications

In 2009–10 no applications were rejected once accepted for full evaluation; however, 33 applications for veterinary medicines and 65 applications for pesticides were

[7] The APVMA does not keep records that differentiate between applications voluntarily withdrawn and those treated as withdrawn by the APVMA. In the same period, 911 applications for veterinary medicines and 1656 applications for pesticides were received.

withdrawn by the applicant or treated by the APVMA as having been withdrawn. While the identification of technical issues once an application is accepted for evaluation can delay the evaluation and finalisation of an application (as discussed below), a number of other factors can contribute to inefficiency in the assessment process.

For example, the Agvet Code enables an applicant to provide new or additional information in relation to an application at any stage of the application process before the application is determined. Currently, applicants regularly submit applications for relatively minor changes and so pass through the initial screening process quickly, and then later make changes to the application during the evaluation process, adding complexity to the assessment.

Allowing changes to applications in this way once they have been accepted by the APVMA has been identified as having a significant impact on the timeliness of the assessment. It places a burden on the APVMA and partner agencies, which are then obliged to take account of the information, often requiring them to undertake additional detailed assessment or re-evaluate part of their assessment. Significantly, where the submission of additional information delays the finalisation of an assessment, this may in turn affect the progress of other unrelated applications in the registration queue, disadvantaging those applicants.

2.2.3 Time frames

APVMA data for the financial years 2006–07 to 2009–10 indicate that the authority met its statutory time frames for 82–90 per cent and 88–96 per cent of pesticide and veterinary medicine applications respectively.

These statistics provide an overall indication of the APVMA's performance, but they are strongly influenced by the high proportion of applications that are administrative in nature and have a short time frame (two to three months). The data indicate that the authority generally has a high success rate meeting statutory time frames in these categories, although it does not routinely meet them in all cases (see Table 1).

For applications that require a detailed technical assessment of one or more aspects—such as those for adding a new use (with statutory time frames of five to 12 months) or applications for the registration of products containing a new active constituent (with time frames of 13 to 15 months—the data indicate that the APVMA's performance against the statutory time frames is much lower. For example, in 2009–10 only 37 per cent and 64 per cent of pesticide and veterinary medicine applications respectively met their statutory time frames of five to 12 months for completion. In the same period, only 36 per cent of pesticide applications and 89 per cent of veterinary medicine applications met their 13–15-month statutory time frame.

It is the APVMA's performance in the categories with time frames of five months or longer that has the most significant impact on the agvet chemical industry. Importantly, applications made in these categories represent a much higher investment by the chemical industry than do administrative applications. The agvet chemical industry seeks to recover this investment though the sale of its product; hence predictability in the regulatory system and in the time to market is essential. Failure of the APVMA to complete applications within the statutory time frames contributes to uncertainty within the industry, potentially affecting decisions to develop agvet chemicals and their availability.

Table 1: Percentage of applications completed within time frame, 2006–07 to 2009–10.[8]

	2006–07	2007–08	2008–09	2009–10
Percentage of 2–3-month category applications completed within time frame				
Pesticides	97%	92%	95%	95%
Veterinary medicines	99%	99%	98%	98%
Percentage of 5–12-month category applications completed within time frame				
Pesticides	64%	47%	38%	37%
Veterinary medicines	88%	71%	60%	64%
Percentage of 13–15-month category applications completed within time frame				
Pesticides	79%	56%	30%	36%
Veterinary medicines	100%	63%	40%	89%

The unpredictability of the current regulatory system (so far as it relates to the statutory time frames for assessment) is likely to be further exacerbated by the lack of substantive alignment between statutory time frames and the total elapsed time frame taken to complete assessment. This unpredictability is compounded by the APVMA not specifying the 'off the clock' period in which applicants are required to correct applications, often resulting in protracted delays at the request of the applicant. For example, for 2009–10 applications in 13–15-month categories, the average total elapsed time for pesticide and veterinary medicine applications was 46.2 and 33.1 months respectively—at least three times and two times the statutory time frame respectively.

This in turn introduces disincentives into the regulatory system and can also contribute to inefficient use of APVMA resources through it having to manage low quality applications. As shown in Table 2, this difference between elapsed and statutory time frames varies considerably across the range of applications and from year to year. This high degree of variation, coupled with the absolute increase in 'real' time taken to assess an application, leads to greater uncertainty and less predictability for business.

[8] Source: http://www.apvma.gov.au/about/reporting/registration.php

Table 2: Applications' average clock-on period and elapsed time, 2006–07 to 2009–10.[9]

	2006–07	2007–08	2008–09	2009–10
Average clock-on period [elapsed time] — 2–3-month applications (months)				
Pesticides	1.2 [5.7]	1.5 [6.8]	1.3 [5.5]	1.3 [5.7]
Veterinary medicines	0.7 [6.3]	1.0 [5.8]	0.9 [7.3]	0.9 [6.5]
Average clock-on period [elapsed time] — 5-month applications (months)				
Pesticides	5.1 [12.7]	6.4 [15.5]	6.9 [16.2]	8.7 [19.4]
Veterinary medicines	4.1 [13.7]	5.3 [12.8]	4.9 [16.4]	5.4 [15.5]
Average clock-on period [elapsed time] — 6–8-month applications (months)				
Pesticides	8.3 [15.5]	7.1 [13.5]	8.2 [16.1]	9.0 [18.2]
Veterinary medicines	4.7 [18.5]	6.1 [17.8]	8.6 [21.1]	9.2 [21.0]
Average clock-on period [elapsed time] — 9–12-month applications (months)				
Pesticides	12.6 [37.9]	10.4 [23.3]	10.8 [22.2]	12.8 [38.0]
Veterinary medicines	No applications	7.6 [26.5]	11.2 [38.0]	11.0 [36.8]
Average clock on period [Elapsed time] — 13–15-month applications (months)				
Pesticides	10.1 [28.9]	16.9 [26.6]	18.0 [41.5]	45.1 [46.2]
Veterinary medicines	5.9 [26.2]	12.0 [35.7]	18.0 [37.5]	10.2 [33.1]

As the Australian National Audit Office (ANAO) noted, 'The APVMA cannot directly control the time taken by applicants to properly complete applications. However, unnecessarily long time frames add to the cost of regulation, for both the APVMA and applicants, and impact on users' access to pesticides and veterinary medicines.'[10]

Stakeholders have suggested that time frames established by the United States Environmental Protection Agency or under European Union regulations provide a more efficient and transparent arrangement. For example, the United States *Pesticide Registration Improvement Act 2003* and the *European Union Regulations 1107/2009* include specific provisions for maximum time limits throughout regulatory processes, such as for the submission of data and information, assessment reports and the regulator's final decision. Further, the US system requires that the applicant and the

[9] Source: http://www.apvma.gov.au/about/reporting/registration.php
[10] ANAO Audit Report No 14, 2006–07, Regulation of Pesticides and Veterinary Medicines

assessing agency must come to a mutual agreement to change the assessment time lines.

2.2.4 Review of existing approvals and registrations

Existing arrangements for the review of agvet chemicals have been criticised by community and environmental stakeholders as being too slow and inefficient to cope with the number of agvet chemicals that have been nominated for review. These groups have recognised that in contrast to other regulators, particularly in Europe and the United States, Australia's regulator has no requirement for the agvet chemicals currently in use to be regularly reviewed. Instead, Australia's approach relies on a relatively ad hoc risk-based system whereby decisions to review a chemical arise from concerns brought to the regulator's attention by the community, registrants themselves, or the regulator's own initiative. This puts the onus on the regulator to build a case to initiate a review, through analysis of information gathered through its own investigation and from overseas regulators. Environmental and community stakeholders argue that the existing review arrangements are not satisfactory and should be reformed to bring them into line with those of comparable overseas regulators.

Many of the currently approved active constituents and the associated registered products were assessed prior to the inception of the NRS. In establishing the National Registration Authority (APVMA's forerunner agency) in the mid-1990s, about 4000 existing state and territory registrations were adopted (grandfathered) by the Commonwealth. It is estimated that the active constituents contained in these 4000 grandfathered products are now associated with more than 9440 of the 9900 currently registered products. While aspects of these approvals and registrations have been assessed by the APVMA through subsequent applications to vary an approval or registration, not all aspects of the individual approvals or registrations have been considered. This opens the possibility that some agvet chemicals that present an unacceptable risk to the Australian community and/or environment remain on the market without appropriate risk management measures in place.

In the period from 1995 to March 2011 the APVMA completed reviews of 71 active constituents. A further individual 28 active constituents (or groups of active constituents) are currently under review and 40 active constituents (or groups of active constituents) have been nominated and prioritised for review. The number of active constituents that have been reviewed, that are currently under review, or have been nominated for review, is around 9 per cent of those that are currently approved.

In 2008 the Productivity Commission's Report on Chemicals and Plastics[11] cited a 2006 ANAO audit of the APVMA's regulation of pesticides and veterinary medicines in which ANAO said it 'considered that it (the APVMA) had reasonable arrangements for identifying and prioritising existing chemicals requiring review'. However, 'even for the relatively small subset of existing chemicals identified and prioritised for review, ANAO noted the slow rate of progress in commencing and completing reviews. The ANAO also found 'that the average time to review an existing product was nearly three years, and this was set to increase because many of the reviews in progress have already taken more than five years'.

The APVMA's current goal is to make five review decisions (either to start or finish a review) each year, meaning the current reviews and priority nominations will not be

[11] Productivity Commission 2008, Chemicals and Plastics Regulation, Research Report, Melbourne.

completed until at least 2033. However, as no statutory period applies to chemical reviews, they can continue indefinitely. A significant factor in the protracted nature of chemical reviews has been the ability for approval holders and registrants to contribute information at any stage of the review. The APVMA also, in requiring data relevant to the review, must set a reasonable period for the provision of data or information. The nature of the information required means that this period usually extends to a number of years, significantly delaying the outcome. Based on past performance, companies may be motivated to delay submitting data if they see advantage in extending a review.

It is broadly recognised that the existing data protection arrangements for reviews do not provide sufficient encouragement to provide data to support a review. These provisions have been criticised by stakeholders on three primary bases: the point at which data protection commences; the period of protection; and the arrangements for negotiating access to data.

An efficient and effective review process that does not unnecessarily remove chemicals from the market depends on the availability of relevant data that meets contemporary standards to address data gaps. To offset the high cost of generating data, effective mechanisms must be in place to protect the owners' rights to that data so that the cost can be recouped. Without adequate protection, there is little incentive to invest in data. If reviews proceed in the absence of data, agvet chemicals may be unnecessarily removed from the market. This will reduce the range of agvet chemicals available to users. In turn, this has the potential to undermine the productivity and competitiveness of Australian primary producers.

A key difference between data protection for approvals and registration and that for chemical review is the commencement point for the protection. While data protection for approvals and registration commences on the date of the regulatory decision, for reviews it commences on the date data is submitted. Because of the length of chemical reviews under the existing system, the protection period has often lapsed before a regulatory decision has been made. Taking into account the point at which data protection commences in relation to a review, the existing periods of data protection provide little, if any, opportunity to recoup the costs associated with that data from the market.

Data protection periods for individual sets of data submitted for a chemical review vary between two and seven years, depending on the nature of the study undertaken. In relation to approvals and registrations, blanket periods of protection apply—three and five years for variation to veterinary medicines and agricultural chemicals, respectively, and eight years for the approval of a new active constituent or products containing a new active constituent for either veterinary medicines and agricultural chemicals.

The purpose of data protection is to allow the originator of protected information (the data provider) with an opportunity to recoup costs associated with producing that data. In relation to data protection for chemical reviews, because several registrants may be involved, provisions exist to help parties reach an agreement over sharing access to, and the costs of, data where parties are unable to do so independently. If the mediation is unsuccessful, the legislation provides for the terms of any compensation to be established by arbitration. These arrangements are necessary to ensure all approval holders and registrants have access to data that allows the continuation of approval or registration following a review where the APVMA is satisfied the statutory tests have been met. Without these provisions, approvals and registrations without access to data would be cancelled. This could result in the cancellation of the registration of many generic agvet chemicals, not because of concerns about their safety but because of a lack of

access to data. The suggestion that there is concern about the arbitration provisions is supported by the fact that they have been triggered on only one occasion.

Companies that supply generic agvet chemicals typically employ a low-overhead business model and do not have their own research capacity. The typical business model includes competing on price, and so companies are sensitive to increases in costs and are likely to withdraw from the market if they cannot pass them on to their customers. If many generic agvet chemicals were to be withdrawn from the market it would not only adversely affect the approval holders and registrants but it would also reduce the number of generic agvet chemicals in the marketplace. This in turn has the potential to reduce competition and increase costs to the agvet chemical users.

2.3 Compliance and enforcement

The APVMA's legislation provides a limited range of compliance enforcement options—between the two extremes of warnings and criminal prosecution. This means that the outcomes are often ineffective or too costly and/or protracted to be of practical use. This makes it difficult for the APVMA to undertake necessary compliance enforcement activities.

For example, veterinary products that are claimed to have therapeutic benefits for animals are required to be registered as veterinary medicines with the APVMA. The APVMA advised the small Australian company producing unregistered veterinary medicines on 14 separate occasions over a decade that its products required registration because of the therapeutic claims made. Rather than actively seeking registration, the company took a range of actions in an effort to avoid being captured by the statutory definition of a veterinary medicine. The limited options available to the APVMA meant that criminal prosecution was its only option. After formal investigation by the APVMA the Commonwealth Director of Public Prosecutions (CDPP) decided to commence prosecution action. The company was successfully prosecuted and a court penalty applied. This resulted in it being uneconomic for the company to continue producing the unregistered products. If the APVMA had the option of establishing an enforceable undertaking, the company could have been required to rectify the claims and descriptions of the unregistered veterinary medicine, cease supply of non-compliant products and undertake to seek APVMA registration.

The legislated requirement to begin a prosecution within two years of an offence hinders the APVMA's capacity to investigate and prosecute some instances of deliberate non-compliance. For example, a medium-sized multinational company intentionally avoided applying to the APVMA for registration of a marine anti-fouling paint to escape paying $40 000 worth of fees and levies on sales of around $1 million over a five-year period, until the APVMA uncovered the breach. Despite the company being found guilty, the fine was calculated on only two years' sales (since the sale of an unregistered product more than two years before the start of the prosecution is not legally considered an offence). A fine calculated on the full five years' sales may have been more appropriate, given the nature of the offence. In such cases the current statutory requirement does not facilitate the administration of a robust system.

In a number of other cases, where the APVMA has unknowingly relied on falsified documents submitted by an applicant, the APVMA has found that it lacks the power to rescind the decision if the fraud occurred more than two years before the offence was discovered. This is of particular concern, as the APVMA has found that it can be difficult to detect deliberate fraud, and it is likely to take more than two years. Not only does this

mean that perpetrators will continue to go unpunished, it is also more likely that the practice will continue, effectively allowing counterfeit products to be sold on the Australian market.

Section 3 Objectives

The overall objective of the reform package is to increase the efficiency and effectiveness of the Commonwealth's regulation of agvet chemicals, including by introducing measures to improve the operation of the APVMA. Reforms will increase predictability and certainty for business, reduce unnecessary regulatory burden, and add to the high level of protection afforded to human health and the environment while promoting competitive and sustainable food, fuel and fibre production.

Section 4 Options and impact analysis

The reform package consists of a range of measures to improve the governance frameworks and operational activities of the APVMA and its regulatory partners; better align regulatory effort with the degree of risk; enable more timely assessments, registrations and reviews; require that agvet chemicals be periodically assessed to ensure they remain safe; and improve community confidence in, and the effectiveness of, the regulatory actions of the APVMA.

The proposed reforms seek to provide a framework through which the APVMA can provide more flexible, timely and streamlined regulation of agvet chemicals without diminishing the level of human and environmental protection the regulatory system currently provides. The reforms will drive improvements to the efficiency of the APVMA's operations, principally by allowing it the flexibility to apply appropriate resources to higher value functions while reducing effort on functions with lesser consequences for protecting human and environmental health and safety. Several reforms are aimed at preventing poor quality applications entering the registration process.

The suite of measures draws on recent advances in the various regulatory approaches adopted in the United States, the European Union, Canada and New Zealand. The options proposed provide the most appropriate mix of measures for an improved legislative, governance and operational framework for regulating agvet chemicals for the Australian industry, community and environmental contexts.

4.1 Options and impacts by measures proposed

4.1.1 Measures group 1

Enhance the consistency, efficiency and transparency of agvet chemicals approvals, registrations and reviews, by:

(i) developing and publishing a risk framework that includes decision-making methodologies, guidelines and standards that apply to the assessment and review of agvet chemicals[12]

[12] Paragraph numbers (i.e. (i) etc.) refer to numbering of measures in Attachment B to the submission for government consideration.

(ii) defining the policy and standard setting responsibilities of the APVMA and its regulatory partners within the risk framework for agvet chemical assessment and review; and

(iii) applying the risk framework to appropriately align the level of assessment and review effort with the hazard of the active constituent and risk of its use in the chemical product.

NOTE: While not strictly regulation, or quasi-regulation, measures (i) and (ii) above inform the rationale behind many of the other measures in this proposal, and will influence the execution of regulation proposed here. Discussion of these measures in this section is provided for context and completeness. No regulation is proposed in relation to this group of measures.

Rationale

This group of measures implements a 2010 election commitment, which was to '…deliver a risk management framework to match the level of regulation with the level of risk and focus resources on the higher risk products. This will also allow approvals of new, safer chemicals to be fast-tracked.'

There are two aims underlying this group of reforms. The main aim is to improve transparency about the regulatory processes of, and consistency in decision making by, the APVMA and its regulatory partners. The second is to enable better alignment of the level of assessment with the level of risk, in line with the policy principles of the national framework consolidated by COAG in August 2010.

Information asymmetries exist between the APVMA, its regulatory partners and applicants. Misunderstandings about the requirements that apply to applications for, or reviews of, approval or registration result in a lack of transparency and predictability in regulatory decision making. This reduces an applicant's motivation and capability to develop a high-quality application, leads to poorer quality inputs to the regulatory system and contributes to delays in the application assessment process. It is also likely to contribute to reduced innovation as investment costs are increased because of higher uncertainty and reduced predictability for critical time-to-market parameters.

Currently, approval and registration decisions require a detailed assessment across a range of criteria, including efficacy and hazards to human health, the environment and trade. This requirement leads to the inappropriate allocation of regulatory resources towards assessments that do not warrant the effort when the risks involved in the use of the product are considered. Further integrating risk-based approaches to agvet chemical assessment by allowing assessment of applications—which the APVMA determines according to its risk framework—to take place against appropriate criteria would better align regulatory effort with the hazard of the active constituent and risk of its use in the chemical product.

Details of measures proposed

It is proposed that the APVMA and its regulatory partners, particularly OCSEH and SEWPaC, develop an overarching risk framework for agvet chemicals. They would be required to develop and publish all relevant guidelines, standards and methodologies that guide regulatory decisions made under the agvet chemicals legislation about the level of risk of a particular product or active constituent, and about the way those risks may be

managed. Importantly, it will clearly show how the level of assessment is aligned to the hazard of the active constituent and risk associated with its use in the chemical product.

The overarching risk framework would set out the risk assessment processes used by the APVMA and its regulatory partners for agvet chemical registration and review, including how assessment is conducted and risks are managed. Beneath this framework technical manuals and guidelines would explain in detail how data is evaluated, hazard characterised, exposure identified and assessed, and risks are managed. These guidelines would include a clear articulation of how the APVMA will have regard to international data and assessments undertaken by comparable regulators.

The detailed material would be relevant to applicants and stakeholders interested in the methodology and parameters for risk assessment as it would inform the requirements for submitting applications for agvet chemical registration or active constituent approval. The risk framework would have similar application to the chemical review program, establishing a rigorous and transparent methodology for prioritising and conducting chemical reviews. The risk framework would also set out the methodology for establishing the duration of the sunset period for registrations and approvals and the priority for re-registration (see measures group 3).

Developing and publishing the risk framework would allow the APVMA and its regulatory partners to expand the limited existing risk-based regulatory approach to streamline applications and expedite the assessment of lower risk products. The requirement for the APVMA to conduct all components of an assessment in every case would be modified to enable this.

For example, all agvet chemical products are currently assessed for their efficacy and for the risk that their use may prejudice trade. Instead, and as provided for in the risk framework, where a chemical is used as part of an integrated pest management regime and not as a sole control, the APVMA could not require applicants to submit efficacy data. As well, in a situation where a veterinary medicine is used only on a companion animal it may not be necessary to assess trade risks as no significant trade in the animal is likely. In all cases health and environmental assessment criteria would continue to apply, though the scale of those assessments would be calibrated to the health and environmental risk of the chemical. The requirement to provide efficacy and trade data has proven to be a barrier to the registration of number of products, as the Australia-specific data requirements are considered to be onerous by multinational companies and overly costly relative to the likely return on investment from a relatively small market. A number of products available in the United States are not registered in Australia for this reason.

Impacts

Codifying and publishing a risk framework would improve transparency and consistency in decision-making. Improving the consistency of the assessment process would enable applicants to more reliably predict the outcome of an assessment—there would be fewer cases of applicants finding that an application they believed to be sound was deemed deficient or rejected. CropLife International estimates that bringing a new crop protection product to market costs more than $250 million and takes about 10 years[13]. The measure should result in increased investment in innovation as certainty about returns

[13] http://www.croplife.org/files/documentspublished/1/en-us/PUB-BR/5743_PUB-BR_2010_11_23_Facts_and_figures_-_The_status_of_global_agriculture_(2010).pdf

on high-cost research and development for new and/or existing products improve. Encouraging new research would also benefit agricultural producers through access to new and innovative products.

The alignment of assessment effort with the level of risk would improve the efficiency of the APVMA's and applicants' use of resources. The agvet chemical industry would have greater capacity to develop low-risk agvet chemicals more quickly and cost-effectively because of the reduction or removal of the costs associated with generating data and information to support the application, as is currently required whether or not the risk of the product warrants that effort. This would also enable more low-risk products available overseas to be registered economically in Australia.

The risk framework would comprise several components and would be developed in full consultation with stakeholders. It is anticipated that an overarching risk framework document would be developed by the end of 2011 to clarify the high-level objectives and provide the strategic guidance that will assist the development of specific components. Benefits would begin to accrue following its publication, and this would continue, as the consultation process is expected to improve transparency and understanding of the system. However, full benefits are not expected to flow for at least some months after the publication of all components, as companies will need time to integrate their improved understanding of the regulatory requirements with their product development and application preparation procedures.

In addition to the overarching risk framework, specific components would deal with public health; occupational health, chemistry and manufacture, residues and trade, and efficacy and safety. These components would be finalised sequentially through 2012 and 2013. They would complement the environmental component, which has already been developed.

Alternatives

An overarching statement of attitudes to and acceptance of risk could be developed at significantly less cost. However, this would provide substantially reduced benefits as it would not improve transparency of decision-making processes or provide for the better alignment of the level of assessment effort with the level of risk.

No other alternatives were identified that would achieve this outcome without undermining the integrity of the NRS. Codifying the risk framework in a legislative instrument was considered unnecessarily restrictive and would make it more difficult to keep it up to date.

4.1.2 Measures group 2

Ensure the ongoing safety of agvet chemicals and improving the effectiveness and efficiency of current agvet chemical review arrangements by implementing a mandatory tiered re-registration and re-approval regime, designed to minimise impacts on affected businesses, by:

(i) introducing sunset provisions on chemical product registrations and active constituent approvals, with differing sunset periods depending on the hazard of the active constituent and risk of its use in the product, as provided for in published risk frameworks;

(ii) introducing an opportunity to apply for the re-registration of a product or re-approval of an active constituent prior to expiry as an extension to the existing registration renewal process or as part of a new approval renewal process

(iii) providing for the registration or approval of a product to be suspended or cancelled through a compliance process (without a chemical review) if, in the re-registration process, a concern arises about a breach of registration requirements

(iv) providing for the registration or approval of a product to be suspended or cancelled following a chemical review process if, in the re-registration process, a concern arises about the product meeting contemporary approval and registration standards

(v) providing for the APVMA to suspend or cancel an approval or registration where the person responsible for the chemical has not provided information in accordance with an APVMA request made in the re-registration and review process

(vii) re-registering a product for another period where the APVMA has no concerns that would prevent it being re-registered.

Rationale

This measure implements a 2010 election commitment, which was to '…put the onus on chemical companies to prove their products remain safe at regular intervals—bringing Australia into line with most regulators in the United States and Europe'.

Australia's regulation system allows for agvet chemicals to be registered indefinitely, subject to the payment of a fee, unless the registration is suspended or cancelled or voluntarily withdrawn by the registrant. A similar arrangement exists for the ongoing approval of active constituents, but without need to renew the approval annually.

Only 4.6 per cent[14] of the products currently registered for use in Australia have been registered on the basis of a new active constituent assessment by the APVMA since it was established in 1995. The remaining products registered for use are based on active constituents and products grandfathered into the National Registration Scheme (NRS) 16 years ago, having been approved under previous state and territory-based arrangements. Many of those chemicals, while thoroughly assessed and found safe against the standards applicable at the time (and reviewed by the Australian Agricultural and Veterinary Chemicals Council), have not been comprehensively reassessed by the APVMA to take account of any new information that has emerged since the initial assessment.

In contrast to other comparable regulators, particularly in Europe and the United States, Australia has no requirement for agvet chemical registrations or active approvals to be regularly reviewed. Instead, Australia's approach relies on an ad hoc system whereby chemicals of concern come to the attention of the regulator through its own analysis, that of its regulatory partners, industry stakeholders and the community. These chemicals may then be the subject of a reconsideration (also known as a review). The current system places the onus on the regulator to demonstrate that an agvet chemical cannot be safely registered, which requires a thorough review, rather than imposing

[14] That is, 454 of the 9894 products currently registered are based on the 268 active constituents approved since 1995.

requirements for the registrant or approval holder to demonstrate that the product will continue to meet the statutory criteria for ongoing registration or approval.

This reform introduces a tiered and targeted agvet product re-registration and active constituent reapproval scheme (simplified to 're-registration' for this RIS) to augment the existing registration renewal and chemical review systems. The measure would apply to all current and future approvals and registrations. This measure responds to community concerns by ensuring that chemicals continue to be registered or approved only when they meet appropriate health and safety standards. The scheme would be built on the principle that re-registration should occur where it has been established, taking account of submissions by the applicant, that there are no reasonable grounds, founded in evidence, to doubt that the product would not meet contemporary standards and would not pose an unacceptable risk to human or environmental health.

Details of measures proposed

Existing provisions within the Agvet Code describe a process for the renewal of agvet chemical registrations on an annual basis. Subject to payment of a fee (currently $430) and any other action the APVMA may take outside the renewal process (such as suspension or cancellation as a result of a chemical review or compliance action), this administrative process maintains the registration of the product for a further year. The existing renewal requirement does not extend to active constituents, which, once approved, can remain on the register indefinitely.

In order to facilitate the commitment to provide for regular opportunities to assess the ongoing safety of registered chemicals, these reforms provide for the existing registration renewal process to be supplemented by an opportunity to apply for re-registration. Unlike registration renewal, there is no need for re-registration to be an annual process. The interval between re-registration opportunities—that is, the time before expiry of registration—can be determined on the basis of the hazard of the active constituent and risk of its use in the chemical product. It is important to note that annual renewal of registrations of chemical products provides an up-to-date list of the products that are being supplied to the market and would continue to operate in conjunction with this reform. This information is useful when assessing the aggregate risk to the community of a particular active constituent.

The risk framework will set out the methodology for establishing the duration of the registration expiry period. As the risk framework has not yet been developed, it is not possible to describe the registration expiry period for different agvet chemicals. However, the frequency of re-registration will be influenced by such factors as the hazard profile of the active constituent the product contains and risk to human health and the environment associated with its use. It is thought that the same period will apply to the registration of both agvet chemicals and the active constituents within the products, and that the re-registration period could typically be in the range of seven to 15 years, which is consistent with stakeholder views. This interval would be subject to later adjustment should the risk framework indicate more or less frequent re-registration is warranted. The requirements would be rolled out progressively over a 10-year period following the completion of the risk framework, so as to avoid an unnecessary spike in work for the APVMA or the regulated community. Accordingly, the first re-registration would occur immediately following finalisation of the risk framework in 2013. Chemicals that pose the most concern would be required to apply for re-registration first.

As re-registration requirements would apply to all registrations and approvals, all approvals holders and registrants who wish to maintain registration and approval would

be required to participate. Respondents will therefore include sole traders, small and medium-sized enterprises and large multinational firms. Individuals and smaller companies that seek registration or approval often use the services of a registration consultant, and it expected that such consultants would assist with meeting the re-registration requirements.

It is most common for companies to be responsible for one chemical. While 80 to 85 per cent are responsible for fewer than 10 chemicals, around 5 per cent of companies are responsible for more than 50 agvet chemicals. Consideration will be given to strategies to manage the workload of this latter group where this is possible without compromising safety.

The proposed re-registration process entails setting a number of gateway criteria at tier 1 to focus attention on any chemicals of concern in a low-cost manner, with those chemicals identified moving to tier 2 for further scoping and assessment to determine the appropriate compliance or review pathway for the chemical, and thereafter to a compliance intervention if appropriate or to tier 3 for a chemical review under a reformed reconsideration process if the concerns identified in tiers 1 and 2 are found to be substantive.

There would be opportunities for review of draft decisions at tiers 2 and 3 as appropriate, with transparency measures developed to inform the market, community and chemical user groups of potential registration changes. The APVMA would be able to suspend or cancel a chemical's registration or approval at all stages of the re-registration process if it finds that the product's continued use would breach the requirements of registration or approval.

Further details on the assessment tiers follow, although the final design of the scheme would be informed by the risk framework, and would be developed by the Department of Agriculture, Fisheries and Forestry, the APVMA and other regulatory partners in consultation with stakeholders. These discussions will enable the requirements for the various tiers described below to be crafted to maximise the likelihood of identifying and removing any dangerous chemicals from the market while at the same time minimising the cost imposed on business and the authority. Stakeholder comments to date, both positive and negative depending on their perspective, appear to have been predicated on the assumption, based on the operation of the European Union scheme that registrants will, as a matter of course, need to provide new data to support ongoing registration[15].

Tier 1

The tier 1 process seeks to identify chemicals that might be the subject of further scrutiny over their suitability for registration or approval. Tier 1 would involve an administrative (as distinct from technical or scientific) assessment, with individuals or companies responsible for approved chemicals and registered products required to answer a series of questions relating to ongoing approval or registration.

Applicants that would be required to answer these questions would be those holding approvals or registrations. It is therefore reasonable to expect that they will be familiar with the type of information that will be requested. The questions asked would not require registrants to provide information that they could not already be

[15] CropLife estimated that the cost of generating new data can range from $100 000 to $500 000 depending on the studies involved.

reasonably expected to have, through either their compliance with the conditions of registration or approval or their commercial activities relating to their supply of a product for sale. For example, registrants are currently obliged to comply with conditions of approval or registration, provide the APVMA with any new information (under section 161 of the Agvet Code) that contradicts information previously provided, and report adverse experiences. The re-registration questions would be structured to promote administrative efficiency for companies and the APVMA through the use of smart forms. The questions asked might include:

- Has the current approval/registration status of this product, any of its constituents or any substantially similar products that you are aware of changed in an OECD member country since your current approval/registration was provided in Australia? If yes, please provide details.

- Has any decision been made by a government and/or under a treaty to register, review or de-register or list your product in an overseas market since the product was first registered, or last re-registered? (This question addresses, in part, an election commitment to ensure that, if chemicals are banned in a comparable market overseas, this would trigger a process for review of domestic use of the chemical.)

- Are you aware of any adverse experiences as a result of using this chemical product (either in Australia or elsewhere) that have not been reported to the APVMA? If yes, please provide details.

- Are you aware of any relevant information in relation to your product, or the active constituents that it contains, that potentially raises concerns about the safety of the product that has not been submitted to the APVMA? If yes, please provide details.

- Are you aware of any research that potentially relates to the safety of this product or any of its constituents that is in progress or has been completed and has not been submitted to the APVMA? If yes, please provide details.

- Have you made changes to the constituents of the chemical product since this product was approved by the APVMA? If so, are these changes within prescribed tolerances for this product? If not, please provide details.

- Have you made changes to the concentration, composition or purity of any of the constituents of the chemical product since this product was approved by the APVMA? If so, are these changes within prescribed tolerances for this product? If not, please provide details.

Registrants would also be required to declare that their product continues to comply with conditions of registration and any statutory conditions applicable, and that they know of no reason why the product should not be registered for a further period.

The APVMA would then undertake targeted audits to compare the information provided with intelligence it has gathered, including information from overseas regulators, and a range of significant penalties would be available to respond appropriately to false declarations. Where the administrative check raises no concerns, the chemical or product would be re-registered, while the others would proceed to tier 2 (below).

Tier 2

The tier 2 process will be applied to any application for re-registration that was not granted at tier 1 and would enable the APVMA to undertake a more detailed technical examination of the application for re-registration. The tier 2 assessment would determine whether the issues about the product identified in tier 1 were worthy of further investigation, and what kind of investigation should take place.

Following a tier 2 assessment, applications for re registration would be:

- granted, subject either to no changes to conditions of registration or with revised conditions of registration following compliance or administrative action
- referred for review in tier 3, or
- rejected, with applicants having the opportunity to apply anew for registration or approval.

Applications for re-registration that are recommended for chemical review would be placed in the queue for the (existing, though reformed) chemical review process. Tier 2 assessment would determine the priority for the particular re-registration within the queue for review, the scope of the review (including whether a single product, all products containing a particular active constituent, or an entire class of active constituents are to be reviewed) and, within this, the components of the existing approval or registration that are to be reviewed.

Applications for re-registration that are recommended for compliance action would be subject to an investigation by the APVMA using its existing processes and a new, graduated compliance regime. Applications for re-registration that are recommended for administrative action may be subject to revised conditions of approval or registration or have the particulars of the registration or approval revised.

The tier 2 process would determine whether it is necessary to request further information from the registrant and what that information should be. At tier 2, the APVMA may seek information from overseas regulators about their registration decisions or seek advice from regulatory partners on component assessments or particular issues (e.g. from OCSEH on toxicology or from SEWPaC on environmental impacts).

The APVMA would request a submission from the registration or approval holder before doing the tier two assessment.

Tier 3

The tier 3 review process would be governed by the results of the tier 2 assessment as to the priority, scope and information required for a chemical review. Following a tier 3 process, applications for re-registration would be either:

- granted, subject to no changes to conditions of registration or with revised conditions of registration, or
- rejected, with applicants having the opportunity to apply anew for registration or approval.

Following the review, if the APVMA is satisfied that the risks posed by the chemical or product can be managed according to current criteria for approval or registration, it would be re-registered.

The APVMA would request a submission from the registration or approval holder before doing the tier 3 assessment. The request would be based on the results of the tier 2 process, and would ask for any information or data required to complete the tier 3 process.

If a registrant fails to provide information in accordance with an APVMA request made in the re-registration process (at any of tiers 1, 2 or 3), the APVMA would be able to suspend or cancel the registration. This addresses a difficulty with the current review system whereby reviews are often extended inappropriately because responsible persons for a chemical do not provide data, or provide it late. This allows the registration to continue for the extended period of the review.

Impacts

The key benefit of this reform is that it would better protect human health and the environment by implementing a systematic and regular process to determine whether registered agvet chemicals and approved active constituents continue to meet the statutory tests for registration or approval.

The proposed tiered, risk-based approach for re-registration would identify those agvet chemicals of highest potential risk and target the APVMA's resources toward their assessment. This targeted risk- based approach would ensure that re-registration of lower risk chemicals would not be subject to unnecessary regulatory costs that would ultimately impact on chemical users through higher chemical costs or availability of agvet chemicals. This would be achieved by limiting the administrative burden and subsequent costs at tiers 1 and 2 through requiring registrants to provide only information that they could reasonably be expected to have access to, or make available at low cost.

Under the existing agvet chemicals framework, agvet product registrants and approval holders have a responsibility to ensure the ongoing safety of their products. This is embodied in their requirement to by comply with the conditions of approval and their obligation to inform the APVMA of any information that contradicts information previously provided or that indicates the agvet product or active constituent may be harmful to human health or the environment. This reform would place the onus on registrants and approval holders to fulfil this obligation, requiring the agvet chemical industry to actively contribute to the APVMA's management of the agvet chemicals. However, the requirements in the first two tiers would be much less than those for registering a new chemical or seeking approval of a new use. The tier 3 requirements would be equivalent, but these would apply to only a very small proportion of companies.

This approach would encourage the removal of unutilised but currently registered chemicals from the agvet chemical register. This would ensure not only that the APVMA's records continued to accurately reflect registrations and approvals in Australia but also that the APVMA's resources were focused on those products that are in use and therefore may pose a risk to human health, trade and the environment. The costs of this reform would be in providing resources for the assessment of applications at each tier and in the administrative costs associated with the setup and operation of the program. Phasing the system in over 10 years would see the tier 1 administrative assessment check applied to approximately 10 per cent of the registered products and active constituents annually, resulting in about 1000 applications per annum.

The proportion of applications referred to tier 2 would be expected to vary from year to year depending on the agvet chemicals and active constituents nominated for re-registration. The number of applications referred to tier 2 would be managed by establishing thresholds at tier 1, guided by the risk framework, so that only those applications that indicate potential non-compliance or risk over and above that already accepted by the APVMA are referred to tier 2. The lack of evidence of widespread problems indicates that most applicants and approval holders currently comply with their obligations under the Agvet Code. It is envisaged that these factors would limit the number of applications referred to tier 2 to no more than 10 per cent of the applications received. This objective would be facilitated by giving careful consideration to the design of the tier 1 criteria, in consultation with stakeholders.

Depending on the issues identified, tier 2 assessment would require evaluation by technical staff or compliance officers. The impact on these resources is difficult to quantify and would be influenced by the extent of new information provided to the APVMA requiring assessment or compliance action. However, in the absence of evidence of widespread problems resulting from the use of the current inventory of chemicals[16], it is anticipated that not more than 10 per cent of tier 2 assessments (i.e. less than 10 per annum) would be referred to tier 3.

Of the existing 9900 registered agvet chemical (containing one or more of the 780 approved active constituents), the APVMA currently has 28 active constituents or chemical groups on its 'chemicals under review' list. The APVMA has also identified and prioritised 40 chemicals that need to be reviewed. The revised process would better inform the APVMA's agvet chemical review and compliance programs, improving their efficiency and better targeting the APVMA's resources to the management of higher risk registrations and approvals. It is anticipated that the number of chemicals under review at any point in time would not change significantly, as in the initial re-registration cycle many of the agvet chemicals and active constituents identified for review would have already been prioritised for review.

Where a chemical product or active constituent has been referred to tier 3 for assessment, as with the current statutory review process, it is possible that registrants will not seek re-registration because they decide that the costs of generating additional data outweigh the commercial returns available. In this circumstance, it is possible that otherwise useful (and potentially safe chemicals) will be withdrawn from the market. Stakeholder estimates of the cost of generating additional data suggest that this impact could be significant for those registrants subject to tier 3 assessment. For example, CropLife Australia estimated in its supplementary submission that data costs would range from $100 000 to $500 000 per re-registration. However, the actual impact would also depend on market factors, and the varying degree to which registrants have to generate the required additional data. For example, a market dominated by a high number of generic products would expected to be most adversely affected, as it is difficult to capture the additional commercial gain needed to cover the regulatory costs of review and registrants of generic products do not have the capability to generate the types of additional data required.

Strategies to mitigate these impacts include ensuring that chemicals entering tier 3 of the re-registration are the result of a highly targeted, risk-based approach deployed at

[16] The Toxics Network has identified at list of 123 chemicals it claims are most dangerous on the basis of regulatory settings overseas and therefore in need of review, but the APVMA disputes the claim that these chemicals necessarily pose a threat in Australia.

tiers 1 and 2 of the process. In this regard, it is envisaged that the numbers of chemicals referred to tier 3 in any year would broadly equate to the existing numbers of review nominations—thereby ensuring that there is no undue additional regulatory burden on business at this stage in the process.

Phasing in of the re-registration system on the basis of risk, coupled with Commonwealth funding provided to assist with addressing the backlog of existing reviews, would mitigate the imposition of otherwise high start-up costs on the APVMA and business.

Additionally, reforms to data protection in relation to chemical reviews would provide registrants with an avenue to recoup (from the market) the costs of generating additional data to meet the requirements of product re-registration.

Alternatives

Possible alternatives to these measures include making incremental improvements to the existing chemical review arrangements or implementing a scheme that more closely reflects those established in the United States (US) (for older chemicals) and the European Union (EU). On the latter, while there are some fundamental differences between those two schemes, both implement a systematic approach to the review of pesticide registrations. Community and environmental stakeholders consider that a comprehensive, systematic approach is necessary, while chemical industry and user groups argue that no case has been made to change the existing system.

The US Environmental Protection Agency (EPA) is responsible for reassessing the safety of older pesticide registrations against modern health and environmental testing standards. The US re-registration eligibility system for agricultural chemicals, which became law in 1988, mandated the accelerated review of all active constituents in pesticides registered before 1984, to be undertaken within 15 years. The system requires the comprehensive assessment (known as re-registration eligibility decisions or REDs) of all pesticides to ensure they meet current scientific and regulatory standards. Priority for review is based on the risk profile of the active constituent contained in the registered products. This risk is largely determined by examining the extent of exposure to people and the environment in combination with the hazard posed by the active constituents in the product. Subsequent legislative changes in 2004 mandated the completion of REDs for pesticides with food uses by August 2006 and all remaining non-food use pesticides by October 2008. The re-registration program encompasses approximately 1150 pesticide active ingredients organised into 613 cases or related groups of chemicals. A total of 229 of these cases were cancelled in the early years of the re-registration program. The EPA had completed 384 REDs at August 2008.

Following an EPA decision to declare a pesticide active constituent eligible for re-registration, individual end-use products that contain the active ingredient were required to be re-registered. Through this process, known as product re-registration, the EPA determines whether the risk management measures called for in REDs are reflected on individual pesticide product labels. In 2010 it was reported that the cumulative total of products subject to re-registration was 22 039. Of these, 4369 were re-registered, 1179 had their registration amended, 7412 had their registration cancelled and 9059 had actions pending. EPA plans to complete the last product re-registration decisions by 2014[17].

[17] http://edocket.access.gpo.gov/2011/pdf/2011-4649.pdf

In parallel to the re-registration program, EPA began implementing registration review starting in early 2007 to continue the re-evaluation of active constituents on a 15-year cycle. This new program ensures that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides will continue to meet contemporary standards.

European pesticide review system has recently been reformed. Building on the partially successful reforms initiated in 1994, from June 2011 a new regulation for placing plant protection products in the market and renewing approvals is being introduced. This system is predominantly hazard-based, and it introduces strict new hazard criteria based on the properties of the active constituent. Rather than systematically reviewing against all health and environmental criteria, the new approach requests limited data so that only additional requirements since registration need be addressed. The earlier scheme provided for the full re-evaluation of all active constituents already on the market prior to 1993. At March 2009 it was reported that this scheme had assessed some 1000 active constituents, of which about 26 per cent passed the harmonised EU safety assessment. About 67 per cent of the active constituents were eliminated from the assessment because dossiers were not submitted or were incomplete or the application was withdrawn by industry. Products associated with these active constituents became ineligible for sale within the EU. A further 7 per cent of substances failed the review and have been removed from the market because of concerns about their safety in respect of human health and the environment. Adenäuer and Witzke (2008)[18] modelled the possible impacts of amendments proposed at that time to EU Council Directive (91/414/EEC) of 15 July 1991, which regulates the placing of plant protection products on the market. They found that price effects induced would have strong impacts on EU and international markets. For example, they estimated between 26 and 62 per cent reductions in wheat yields, depending on the reforms adopted.

To expedite the re-registration process, the US Congress authorised the EPA to collect fees from pesticide manufacturers. In 2010 the EPA reported $64.5 million expenditure on re-registration and the Expedited Processing Fund. Of this, $40.0 million came from government appropriation. For comparison, the registration sections of EPA spent $57.3 million, of which $39.1 million is provided through government appropriation[19]. In 2011 the EPA noted that currently those who directly benefit from EPA's registration services cover only a fraction of the costs to operate the program, leaving the general taxpayer to shoulder the remaining burden, and it outlines a proposal to collect an additional $17 million towards registration and $25 million towards re-registration from industry in order to more closely align fee collections with program costs in 2012.[20]

While no data on the cost to EU regulatory authorities are readily available, the size and scope of its re-registration system suggest that the cost to the regulatory agencies would be high. To implement similar arrangements, it is anticipated that the APVMA would require significant funding over and above that required for the preferred option. These systems have also resulted in a significant loss of chemicals available to users. It is possible that some of these chemicals should not have been reregistered for safety reasons. However, a significant proportion would not have been re-registered because it was not commercially viable for the companies responsible to defend the products.

[18] http://www.bgcpa.eu/DOC_17993_Eurocare_Bonn_report.pdf
[19] www.epa.gov/pesticides/fees/2010annual.../pria_annual_report_2010.pdf
[20] http://nepis.epa.gov/EPA/html/DLwait.htm?url=/Adobe/PDF/P100A4HZ.PDF

While implementing an EU-style system would enhance agvet chemical review arrangements by comprehensively revisiting each registration and approval, it does not reflect Australia's risk-based policy approach to agvet chemical regulation. Likewise, the US system requires that all products are reviewed, irrespective of the risk they pose. Therefore, adopting either approach would require the unnecessary detailed assessment of the majority of the chemical inventory. Without substantial budget funding, this would result in a large-scale loss of chemicals from the Australian market, which would have significant negative impact not only on agriculture but also on the environment through loss control options for environmental pests.

Implementation of a comprehensive re-registration scheme of all approvals and agvet products does not allow for the alignment of risk with regulatory effort in the same way that a tiered assessment process (as described above) that identifies approvals and agvet chemicals of greatest risk concern would. It would also fail to reflect the capacity of the Australian market to absorb the regulatory and business costs associated with these systems. In the absence of evidence of widespread problems with the current inventory of agvet chemicals, it would be imprudent to pursue such a scheme in Australia. The US and EU reforms have resulted in unmanageable workloads for regulators and industry alike. In the EU the 1993 reforms resulted in the loss of many useful chemicals.

It is expected, therefore, that the Australian agricultural sector would be significantly affected by a US or EU-style re-registration system. In particular, it is likely to result in the cancellation of product registration, not necessarily as a result of an undue risk to human health and safety or the environment but rather as a result of the cost to the agvet chemical industry associated with meeting the requirements for re-registration. This would ultimately reduce the number of pest control and animal health products available to the sector, and thereby adversely affect its productivity.

There are major differences between the European, US and Australian commercial environments—principally in respect of the relatively small size of the Australian agricultural sector in comparison to the European sector and the prevalence of generic chemical use in Australia. The capacity for agvet chemical companies to recover the cost of an extensive re-registration process is greater in the US and Europe than it is in Australia. Generic agvet chemicals provide an important means of bringing competitive pressure to bear on pioneer or innovator products and therefore assist in managing the costs of agvet chemicals (which currently account for around 17 per cent of total farm costs). Additionally, generic chemicals provide important access to chemicals that are no longer within patent, and may not continue to be supplied by the pioneer or innovator registrants. While the APVMA does not specifically record the number of generic chemical registrations, from 15 March 1995 to 27 March 2011, 85 per cent of all new APVMA registrations were 'similar to', 'closely similar to' and 'repacks' of existing products.. Within the APVMA Pesticides Program 90.6 per cent of new product registrations have been for images and in the Veterinary Medicines Program 66.7 per cent of new product registrations are for image products[20]. It is therefore reasonable to assume that the sale of generic agvet chemicals represents a large portion of the chemical market.

Further, irrespective of whether a company is a producer of generic chemicals or a primary registrant, it is likely that a large number of companies would be unwilling to incur the high cost of further data generation. This arises because of the more limited opportunity to amortise the high costs of data generation over a relatively small

[20] Note: for commercial reasons pioneer products are often repackaged by the original registrants (for marketing purposes). Therefore, not all image registrations are generic products.

agricultural sector (which notionally services around 60 million people—including export markets), as compared to the European market where companies service an agricultural sector that supports a combined domestic European population of around 500 million people.

The alternative approach of incremental improvements to the existing chemical review approach is not considered to be sufficient to meet the Commonwealth's stated objective to '... put the onus on chemical companies to prove their products remain safe at regular intervals—bringing Australia into line with most regulators in the United States and Europe'.

4.1.3 Measures group 3

Introduce reform measures to improve the efficiency of the application process for agvet chemical approvals and registrations, and improve the timeliness of agvet chemical approvals, registrations and chemical reviews, including legislation where necessary, by:

(i) including structured, upfront pre-application assistance for applicants and allowing the APVMA to recover the costs of any additional assistance it provides

Rationale and details of measures proposed

One of the principal inefficiencies with the assessment process for agvet chemical approvals and registrations is the time the APVMA is obliged to dedicate to dealing with lower quality applications.

The objective of the proposed measures is to prevent poor quality applications from entering the system by improving applicants' access to the APVMA and providing an opportunity for prospective applicants to seek pre-application advice. This service would enable applicants to submit applications that are complete and of an appropriate standard for assessment, reducing the likelihood that they will be rejected by the APVMA at either the preliminary assessment or assessment stage.

This reform would enhance the APVMA's ability to meet assessment time frames and improve certainty for applicants by improving the quality of applications and reducing the amount of effort and resources the APVMA applies to processing and assessing applications that are in some way deficient. This measure would be complemented by, and to an extent depends on, reforms discussed earlier (measures Group 1) to improve the transparency of the APVMA's approach to assessing applications.

Applicants would be offered a one-off upfront assistance opportunity to allow them to clarify the requirements for an application before lodging it with the APVMA. The cost of this opportunity to the applicant would be offset by an equivalent reduction in the application fee for any application that relied on this assistance. This reform would be accompanied by changes to APVMA processes for dealing with applications to reduce inappropriate calls on APVMA resources and allow the APVMA to charge for any assistance it provides beyond that initial pre-application assistance.

Impact

This reform would benefit individuals and companies applying for active constituent approvals and product registrations by enabling them to confirm the requirements before they submit their application to the APVMA. This would give applicants greater certainty

about whether their application includes all the necessary information for efficient assessment.

The reform would be of greatest benefit to companies that have little experience in making applications or that do so infrequently. Applications made by these sectors of the industry tend to have the highest error rate. Larger and more established agvet chemical companies could also benefit from the service, but are expected to use it less often.

A number of stakeholders have expressed concern that providing this service would result in higher fees for all applicants and that infrequent users will effectively subsidise those that use it more frequently. Concerns were also raised about the potential for applicants to use the APVMA in place of registration consultants engaged on a commercial basis. Although this measure would institutionalise a limited cross-subsidy between different groups of applicants, it would reduce the effort the APVMA puts into administering applications that do not meet the required standards and which represent a more substantial cross-subsidisation between different applications.

This reform is expected to increase the call on the APVMA's resources prior to an application being made. The APVMA already assists applicants when requested, but the terms under which this service is offered are unclear, and none of the costs are recovered. This measure would formalise arrangements and terms under which the advice is given.

The reform would decrease the number of applications received by the APVMA that are found to be deficient. This would reduce the effort that the APVMA dedicates to rectifying applications (by identifying problems and advising applicants) and to rejecting them. The reform would also allow the APVMA to recover the cost associated with providing advice beyond the initial meeting. Applicants that inappropriately rely on the APVMA's resources to develop their applications under the current system would be required to pay the true cost of that service.

Alternatives[21]

This measure is one of several aimed at reducing the likelihood of poor quality or incomplete applications being submitted to the APVMA. No alternatives to these measures that would achieve this outcome were identified.

Not making this change would result in a continuation of the existing unsatisfactory arrangements. Without this change, the effectiveness of the other reforms to improve the efficiency of the application process would be reduced.

[Introduce reform measures to improve the efficiency of the application process for agvet chemical approvals and registrations, and improve the timeliness of agvet chemical approvals, registrations and chemical reviews, including legislation where necessary, by:]

(ii) limiting the APVMA's initial assessment of applications to an administrative check on lodgement to ensure that accepted applications meet administrative criteria, before proceeding to any assessment

[21] NB Alternatives generally applicable to the measures in this group are addressed at the end of section 4.1.3

(iii) preventing changes to an application at the request of an applicant after it has been accepted by the APVMA

(iv) enhancing the APVMA's capacity to make efficient and timely decisions by requiring it to reject an application for approval or registration if it is found to be deficient in the initial assessment, or if it cannot be corrected in a reasonable time frame, or where an applicant has not corrected deficiencies in accordance with an APVMA request, with fees paid forfeited.

Rationale and details of measures proposed

This measure has a similar objective to that of measure (i) above: to limit the number of substandard quality applications that the APVMA assesses and to improve the APVMA's ability to deal with lesser quality applications. It will also reduce the opportunity of applicants to inappropriately rely on the expert assistance of the APVMA to improve the quality of their applications.

Several measures are planned to improve the efficiency of the APVMA's initial assessment and the evaluation of an application after it has been accepted. It is proposed that:

- by limiting the APVMA's initial assessment of applications to an administrative check on lodgement, applications will be accepted by the APVMA and progress to the assessment phase in a timely way, or will be rejected with a statement of reasons. The current practice of allowing applicants to rectify applications during the initial assessment phase would cease, requiring them to be rectified and resubmitted prior to further consideration by the APVMA

- opportunities to vary an application once accepted would be limited to those circumstances where the APVMA considers it efficient and reasonable to make the change, and then only at the APVMA's request. This would allow the APVMA to allocate its resources to those applications that are both administratively and technically complete, enabling it improve its performance against statutory time frames

- in support of the measures outlined above, the APVMA would be required to reject an application for approval or registration if it was found to be deficient in the initial assessment, or if the application cannot or has not been be corrected in a reasonable time in accordance with an APVMA request.

Combined, these measures place the onus firmly on applicants to ensure that their applications are complete and of a sufficient quality to enable the APVMA to undertake both the initial and subsequent detailed assessment within statutory time frames.

Impact

The change proposed to the APVMA's initial assessment process would make the process more predictable for applicants. It would ensure that applications that were administratively complete would be accepted and progress to the evaluation stage within the specified time frame. Applicants that meet these requirements would benefit from greater efficiency and transparency at this stage of the process. These changes would adversely affect only those applicants who do not or cannot comply with the APVMA's requirements or seek to change an application after it has been accepted.

Once accepted, the only changes that could be made to an application would be those that are made at the direction of the APVMA. This would remove current provisions that allow applicants to provide new or altered information at any stage of the process prior to an application being determined. Changes to applications once they have been accepted by the APVMA affect the timeliness not only of that assessment but also of other applications. Again, this measure has negative impacts only for applicants who submit an application that is not entirely suitable for assessment. It would benefit applicants submitting suitable applications by improving the timeliness of assessment processes. It would benefit the APVMA by improving its ability to focus resources on productive assessment effort.

These reforms could increase the number of applications that are withdrawn by the applicant or that are rejected by the APVMA. Complementary reforms, such as those described in measures group 1 and elsewhere in measures group 3 (viii, xi), would provide all applicants with the information necessary to limit the circumstances in which this will occur. As these measures take effect, the number of applications withdrawn or rejected is expected to decrease to below the current level.

Alternatives

No alternatives were identified that would achieve these outcomes. Limiting the scope of this reform or not implementing any of these elements would reduce the extent to which this reform is effective.

[Introduce reform measures to improve the efficiency of the application process for agvet chemical approvals and registrations, and improve the timeliness of agvet chemical approvals, registrations and chemical reviews, including legislation where necessary, by:]

(v) introducing a statutory period for completing a review

Rationale and details of measure proposed

The existing agvet chemical review program has been criticised because reviews take too long. This is supported by the findings of the Australian National Audit Office, which in 2006 found 'that the average time taken to complete a review is increasing as a number of these reviews have already taken, on average, five years and eight months. Fifteen reviews had taken significantly longer'[22].

Inefficiencies in the existing agvet chemical review arrangements have resulted in a significant backlog. Reviews are not currently subject to any statutory guidance about their expected duration and may continue indefinitely.

More significantly, the arrangements give rise to questions about the efficacy of the review program in protecting human health and the environment from the ongoing risks of agvet chemical use. Reviewed chemicals are permitted to be sold during the review.

To reduce the backlog of chemical reviews and improve the timeliness with which new nominations are dealt with, it is necessary to establish a statutory time frame for the completion of reviews (that includes all phases of the assessment).

[22] http://www.anao.gov.au/download.cfm?item_id=77CD23EF1560A6E8AAF3A0840E81C731&binary_id=560EF7611560A6E8AA706CA704DC4BF3

Complementary reforms, such as the introduction of a re-registration scheme (measure 2(iv)), would affect the existing chemical review program. The re-registration program will not only influence the priority list of agvet chemicals reviews but could also be expected to add to it.

Impacts

Establishing statutory time frames for reviews would enable the APVMA to schedule its review activities and work systematically through all nominations. It would provide clear performance targets for the APVMA, and enable it and its regulatory partners to allocate resources to review activities accordingly.

Not making this change would mean that the backlog of agvet chemical reviews, and ongoing delays in finalising reviews, would continue. It would also see a continuation of stakeholder concerns about the efficiency of the agvet chemical review program and the level of protection it provides to human health and the environment.

Establishing a statutory time frame for the completion of reviews, in conjunction with prioritising existing and new nominations according to a risk framework, would assure stakeholders that the APVMA was addressing the backlog of chemical reviews in a timely fashion. These measures would also provide confidence that regulation of agvet chemicals is effective, and that only agvet chemicals that are found to meet contemporary human health and safety and environmental standards remain registered.

Establishing statutory time frames for completing chemical reviews will also enable reviews to be scheduled. The scheduling of reviews would significantly improve the efficiency of the review program by providing early notification of an impending review. This would allow registrants and approval holders the opportunity to gather data ahead of the review to address data gaps identified by the APVMA during its scoping. This would not only allow the APVMA to undertake its assessment on a comprehensive data set, preventing unnecessary delays in the final decision, but would also limit the extent to which agvet chemicals are unnecessarily removed from the market because of a lack of supporting information.

Alternatives

No alternatives were identified for this specific measure. Non-regulatory options were dismissed because of the commercial advantage registrants could gain by delaying the provision of data for chemical reviews.

[Introduce reform measures to improve the efficiency of the application process for agvet chemical approvals and registrations, and improve the timeliness of agvet chemical approvals, registrations and chemical reviews, including legislation where necessary, by:]

(vi) including all stages of the consideration and assessment process in the statutory periods for determining applications for approval or registration or for completing a review

(vii) establishing set time frames for applicants to submit information or to correct deficiencies as requested by the APVMA

(viii) mandating that any extensions to set time frames (as discussed at paragraph 1(vii) above) be mutually agreed by the APVMA and the applicant (if agreement is not reached the APVMA is to determine the application as it stands)

Rationale

Currently the statutory time frame for the APVMA to determine an application excludes any time taken by the applicant to rectify it in response to deficiencies identified by the APVMA. While an applicant is responding to deficiencies, the statutory clock is stopped. There is no limit to the number of requests the APVMA can make of the applicant or the number of times the clock can be stopped. Additionally, there are no strict time frames for the applicant to respond to the APVMA.

This system has been criticised by stakeholders, who suggest the 'stop-the-clock' provisions mean that the statutory time frame is not a good indicator of the time it will take for the application to be determined by the APVMA. The time frame is equally unpredictable for the APVMA, as the duration of the stoppage is largely determined by the applicant.

With chemical reviews, the finalisation of a review can be delayed where the APVMA allows a long period for registrants and approval holders to submit information in response to identified data gaps. The opportunity for registrants or approval holders to negotiate this period, where no statutory period for the completion of a review applies, has in the past significantly delayed review outcomes. Such delays can benefit the registrants and approval holders by allowing the product to remain on the market. Delays are, however, undesirable for the APVMA and the community.

Details of measures proposed

These reforms propose to include all the time involved (i.e. the period from when an application is accepted to the making of a regulatory decision, including time for the applicant to rectify the application) in a single elapsed time frame within which the APVMA must determine the application. The elapsed time frame for each application category would comprise a minimum time frame that applies where the APVMA does not require the application to be rectified and a maximum time frame that applies where rectification by the applicant is required.

The introduction of total elapsed time frames for completing the assessment of applications (measure 3(vi)) and reviews (measure 3(v)) requires that set time frames be established for applicants to rectify an application or for registrants and approval holders to contribute information to a review, if requested to do so by the APVMA.

In circumstances where the requested information cannot be provided in the set time, the applicant (in relation to an application) or registrant/approval holder (in relation to a review) would be offered the opportunity to agree on an extension with the APVMA. This would occur only where the extension could be accommodated within the maximum elapsed time frame. Where the APVMA does not receive information within the set or mutually agreed time frame, it would be required to determine the application or review on the basis of the information it holds (with the prospect of rejection).

Impacts

Not making this change would see a continuation of the existing arrangements that have resulted in delays in the assessment of applications for registration and chemical reviews.

In relation to an application for registration or approval, this reform would provide a high degree of certainty for applicants as to the timeliness of the APVMA's decisions. As with the other reform proposals, the potential exists for more applications to be rejected compared with the existing arrangements, as opportunities for the applicant to rectify an application would be limited. A number of complementary reforms (see measures groups 1 and 3) are designed to help applicants meet the quality standard for applications, and would limit the number of applications that are refused. It should also be noted that measure 3(viii) provides some flexibility to these arrangements within the maximum statutory time frame, where there is mutual agreement between the APVMA and the applicant.

This reform would have adverse impacts for applicants whose applications are incomplete or deficient in any aspect and who cannot or do not responded to an APVMA request to rectify them within the specified time frame. Applications that are rejected would forfeit the application fee, and the applicant would be required to make a new application.

These changes, in conjunction with measure 3(iii), would reduce the number of applications that are not determined by the APVMA within the statutory time frame. These changes would enable the APVMA to make timely decisions and allow more effective use of its resources, and those of its partner agencies.

The changes, when made in relation to the APVMA's consideration of an application, are not expected to adversely affect agvet chemical users or the community.

In relation to chemical reviews and in conjunction with the proposed statutory time frames for reviews (3(v)), there are considerable benefits for the community. Community concerns about the timely conclusion of reviews would be addressed, as registrants and approval holders would not be able to negotiate lengthy periods in which to provide data once a review has commenced. A more efficient review process would provide assurance that the regulatory system is efficient and effective in protecting human health and the environment.

Registrants and approval holders may be affected by this change, as the opportunity to provide data once a chemical review has commenced would be limited. However, this impact would be mitigated by the introduction of statutory time frames for chemical review that would enable the APVMA to schedule reviews and communicate data requirements well in advance of the review.

It is possible that, by limiting the opportunities to contribute information to the review process, some information could be excluded from the APVMA's consideration. If this information were pivotal, it could change the review outcome. Possible impacts could be that registrations or approvals of agvet chemicals are unnecessarily cancelled, adversely affecting agvet chemical users. Conversely, it could result in suspension or cancellation of the registration or approval of a product that would otherwise remain on the market, adversely affecting human health and the environment. However, limiting the opportunity to provide information in relation to a review decision would not remove opportunities to provide that information through other avenues (such as the registration process if it was considered that registration or approval of an agvet chemical was unnecessarily cancelled) or in support of a subsequent nomination for the review of that chemical.

Alternatives

No alternatives were identified for this specific measure.

[Introduce reform measures to improve the efficiency of the application process for agvet chemical approvals and registrations, and improve the timeliness of agvet chemical approvals, registrations and chemical reviews, including legislation where necessary, by:]

(ix) modifying statutory arrangements for the reconsideration of decisions taken by the APVMA where necessary to support the measure described at 3(iv) above;

Rationale and details of measures proposed

This reform would close a loophole in existing regulations that allows a registrant to submit additional information when applying for reconsideration of an APVMA decision, including information that did not exist at the time of the initial APVMA decision. This approach is consistent with that of other regulatory agencies such as the Therapeutic Goods Administration. The measure would be structured so that it does not limit consideration of information that demonstrates possible harm. Measure 3(iv) provides stronger powers to reject deficient applications and it is anticipated that this will result in increased requests for reconsideration. The current reconsideration process is problematic in that applicants can submit information that was not considered by the original decision maker. This may include new research that requires considerable assessment effort. It is generally inefficient for the APVMA to undertake such assessment in the context of a reconsideration. Knowledge that this loophole exists would undermine other reforms aimed at improving the quality of applications.

Impacts

This measure would support measure 3(iv) described above and would ensure that it had the impacts described there.

Careful drafting of this provision in legislative amendments would avoid any inappropriate reduction in the natural justice and procedural fairness afforded to applicants who seek reconsideration.

Alternatives

No alternatives were identified for this specific measure.

[Introduce reform measures to improve the efficiency of the application process for agvet chemical approvals and registrations, and improve the timeliness of agvet chemical approvals, registrations and chemical reviews, including legislation where necessary, by:]

(x) making complementary improvements to data protection arrangements for data submitted in relation to an application

Rationale and details of measures proposed

This reform is necessary to reduce the impact on applicants where the APVMA makes a decision not to grant an application. Existing data protection arrangements prevent the protection of data in cases where data has been submitted to the APVMA in relation to an application that is not granted. Where that same data is resubmitted and relied on in relation to a subsequent application, that data is currently not eligible for protection.

As data generation represents a significant cost to the agvet chemical industry, a cost it seeks to recoup during the protection period, the loss of data protection as described above has the potential to influence decisions to invest in the development of agvet chemicals. Under the current arrangements there is a strong incentive for applicants to request that the APVMA defer making a decision on an application in order to preserve the opportunity for the data associated with that application to be protected.

Reforms proposed as part of measures group 3 enhance the APVMA's capacity to reject an application that is found to be deficient in the initial assessment, cannot be corrected in a reasonable time frame or has not been corrected in accordance with an APVMA request. This change has the potential to increase the number of applications the APVMA rejects.

Data protection provisions would be amended so that, where data submitted to the APVMA in relation to an application that is not granted is resubmitted and relied on in relation to a subsequent application that is granted by the APVMA, it would be eligible for protection.

This measure does not propose to change any other aspect of data protection as it currently relates to applications for the approval or variation of active constituents or the registration or variation of products.

Impact

This change would benefit applicants by reducing the impact of an APVMA decision not to grant an application. While applicants would forfeit the application fee and be required to make a new application, their right to seek the protection of that data in relation to a subsequent application would be preserved.

No significant impact on the APVMA is expected as a result of this change. No impacts on agvet chemical users or the community are expected.

Alternatives

No alternatives were identified for this specific measure.

[Introduce reform measures to improve the efficiency of the application process for agvet chemical approvals and registrations, and improve the timeliness of agvet chemical approvals, registrations and chemical reviews, including legislation where necessary, by:]

(xi) requiring electronic lodgement of applications and supporting documentation, as far as possible

Rationale and details of measures proposed

The APVMA currently has in place an electronic application and registration system (EARS) that accepts applications that are administrative in nature. The system, which is not currently mandatory, has resulted in significantly faster (more than 40 per cent) finalisation for those applications.

Extension of EARS to cover all application categories would improve the efficiency of the application lodgement process by providing fewer opportunities for errors, reducing

delays in the receipt of applications and improving administrative processes within the APVMA.

EARS and the APVMA's supporting information management and document management systems would be expanded to accept all application categories electronically. It would become mandatory (subject to consideration of the government's accessibility requirements) for all applicants to make applications through EARS.

Impacts

While EARS is expected to result in efficiencies for all application categories, it is recognised that the time savings attributed to the current limited EARS may not universally apply.

It is expected that requiring all applications to be submitted electronically will reduce the amount of time and effort applicants spend preparing and submitting applications. It would reduce the opportunity to make an incorrect or incomplete application that will subsequently be rejected. Based on the current application of EARS, applicants are expected to benefit through more efficient processing of applications, reducing the overall assessment period.

Once fully implemented, the system will also remove the need for applicants to provide a paper-based application accompanied by hard copies of supporting information and data.

Traditional paper-based application systems would be maintained, as needed during a transitional phase, and to ensure that the APVMA's application system meets the government's accessibility requirements in the longer term. This would ensure that no applicant is disadvantaged by the change.

Expanded use of EARS will provide the APVMA with significant administrative efficiencies in the receipt and administrative processing of applications. It would reduce the opportunity for applicants to incorrectly complete forms or omit information from an application. This will reduce the number of applications that do not meet the administrative requirements of the APVMA. The APVMA will need to significantly upgrade its information technology and electronic data management systems. The government has provided funding of $2.3 million for upgrades to the APVMA's information technology infrastructure.

Agvet chemical users and the community are not expected to be affected by this change.

Alternatives

An alternative measure would be to expand the capability of EARS and offer the existing paper based systems in parallel. This would effectively see a continuation of the transitional arrangement described above.

Another alternative would be to provide EARS as a voluntary service, offering a nominal reduction in the application fee to those that use EARS. This option is not preferred as the efficiencies the system provides would apply only to a portion of applications, reducing the impact of this change.

Alternatives to measures group 3

This group of measures seeks to improve timeliness and efficiency of the APVMA's processes. Several alternatives to the various regulatory measures proposed above were considered. Using financial penalties to encourage compliance is not considered appropriate as it would disproportionately affect companies, depending on their capacity to pay. It would add to the administrative load on the APVMA without significantly improving compliance in cases where companies perceived commercial benefits from continuing to exploit deficiencies in the system to get new or changed products onto the market sooner. Introducing punitive measures, such as suspending a company's right to lodge applications in a certain category for a period, was also dismissed as it was considered to be an inappropriate restriction on a company's right to trade and it would add administrative complexity.

4.1.4 Measures group 4

Introduce reform measures to improve the ability of the APVMA to efficiently administer its regulatory decisions to protect human health and safety and the environment, including legislation where necessary, by:

(i) providing the APVMA with a graduated range of compliance enforcement powers, including measures to improve and streamline evidence collection, provide the ability to direct improvements in compliance, divert less serious non-compliance from the court system and strengthen penalties for serious non-compliance, with final details of reforms to be agreed with the Attorney-General.

Rationale and details of measures proposed

The lack of a modern, comprehensive, graduated compliance enforcement regime limits the APVMA's capacity to tailor its response to non-compliance to the seriousness of the issue. To improve the APVMA's ability to enforce compliance with its regulatory decisions, it is proposed to provide it with a graduated range of compliance powers.

The current agvet compliance regime provides limited avenues for responses to instances of non-compliance and allows for only high-level actions, such as recalling a product or initiating a criminal prosecution, or very low-level actions to assist self-regulation (education, warnings). Positive enforcement avenues for low-level regulatory action and other penalties currently do not exist in the Agvet Code. Additional positive enforcement avenues would allow the APVMA to efficiently and effectively deal with the majority of compliance matters, reserving costly high-level regulatory action for serious or repeat offenders.

Details of the compliance measures have yet to be agreed with the Attorney-General. However, it is likely that a range of new powers, allowing the APVMA to give directions and undertake controlled operations, would be sought. A number of other alternatives to criminal prosecution would significantly enhance the range of enforcement tools and options available to the APVMA. These could be warnings and enforceable undertakings, civil penalties, penalty infringement notices (fines), graduated penalties for multiple breaches and a requirement to publish compliance outcomes. This measure would be complemented by improvements to existing compliance powers, addressing circumstances where the APVMA's powers can be shown to be ineffective.

All provisions would be drafted to comply with the Minister for Justice's Guide to Framing Commonwealth Offences, Civil Penalties and Enforcement Powers.

Impacts

Stakeholder submissions to the 'Better Regulation of Agricultural and Veterinary Chemicals' policy discussion paper universally supported enhancements to the APVMA's compliance enforcement capacity.

Strengthening the compliance regime will have little negative impact on the majority of approval holders and registrants, as most comply with the Agvet Code. This reform is expected to increase both the efficiency and effectiveness of the compliance program.

Improvements to the compliance regime would enhance the confidence of community and environmental stakeholders in the regulatory system. It would also provide assurance that human health and safety will be protected, as well as the environment. There would be a small benefit to the majority of approval holders and registrants as a result of the improved confidence in the regulatory system.

Not making this change would see a continuation of the existing compliance regime, which lacks the flexibility to respond compliance issues with measures that appropriately reflect their seriousness.

Alternatives

No alternatives were identified that would achieve this outcome.

[Introduce reform measures to improve the ability of the APVMA to efficiently administer its regulatory decisions to protect human health and safety and the environment, including legislation where necessary, by:]

(ii) enhancing existing controls on active constituents and products to ensure their ongoing quality and integrity by providing for updateable statutory conditions of approval or registration

Rationale and details of measures proposed

The current inability to properly enforce controls on the quality and integrity of agvet chemicals and active constituents potentially exposes the Australian community and environment to unacceptable levels of risk.

Controls on active constituents and products could be significantly improved by allowing the APVMA to update statutory conditions on active constituents and agvet products on an ongoing basis where there is a need to do so. The improvement would be more significant in relation to pesticides because there is no manufacturing licensing scheme as there is for veterinary medicines.

Impacts

The impact on the agvet chemical industry of strengthening the controls on statutory conditions associated with active constituents and agvet products will depend on the nature of the changes to conditions. In some circumstances, this reform will enable the APVMA to impose new conditions on existing approvals and registrations.

It is envisaged that changes to the statutory conditions of approval or registration would be made only where the APVMA determined that a change was necessary to protect health and safety and the environment, or to ensure compliance with other aspects of the Agvet Code.

The circumstances in which the APVMA might update statutory conditions of approval or registration would be guided by the risk framework. This will provide transparency for registrants and approval holders, as well an assurance that the APVMA will not unreasonably update statutory conditions once a registration or approval has been granted.

Improvements to the compliance regime would enhance the confidence of community and environmental stakeholders in the regulatory system. It would also provide assurance that human health and safety will be protected, as well as the environment. There would be a small benefit to the majority of approval holders and registrants as a result of the improved confidence in the regulatory system.

Not making this change would mean that manufacturers of substandard chemicals would continue to be able to sell them, which would have serious implications for the users of agvet chemicals and the community.

Alternatives

Direct controls on manufacturing of pesticides would be a novel approach to addressing this problem. As manufacturers are not required to comply with similar schemes in their major markets, the costs would be considered in the context of the Australian market. This is therefore likely to provide a strong disincentive for the majority of companies to supply the Australian market. Given the possibility of very significant consequences of such an approach, no alternatives that would achieve the required outcome were identified.

4.1.5 Measures group 5

Limit opportunities for criticism and improve administrative efficiency by transferring the levy collection task from the APVMA to another Commonwealth agency, including by legislation where necessary, should it be cost-effective to do so. This measure would be finalised between the Minister for Finance and Deregulation and the Minister for Agriculture, Fisheries and Forestry.

Rationale and details of measure proposed

This measure would reduce the perception of a conflict of interest arising from regulation that requires agvet chemical companies to apply to the APVMA for the registration of a product and subsequently requires the registrant to pay sales-based levies directly to the APVMA. This leads to potential for a perception that the APVMA's judgements about high-sales-value products may be influenced by a desire to maintain revenue.

Impact

Not making this change would mean that current stakeholder concerns about a conflict of interest arising from the APVMA's roles in both agvet chemical regulation and levy collection will continue.

The impact on agvet chemical registrants would be negligible, as the proposal does not include a change to the levy structure or rate.

The reform would be implemented only if it could be demonstrated that shifting the responsibility to another government levy collection agency would be cost-effective compared to the existing arrangements. There may be some small savings from economies of scale available to a larger collection agency. For example, DAFF's Levies Revenue Service has a network of compliance officers who regularly visit its levy payers, which are located in similar locations to the APVMA's. This may result in reduced travel costs in conducting audits. The APVMA currently spends $20 000 per annum on audits.

Alternatives

The transparency measures outlined in measures group 1 would also address these perception issues. No other alternatives were identified that would achieve this outcome.

Section 5 Consultation

5.1 Objective and approach

The primary vehicle for consulting stakeholders about these reforms was a policy discussion paper. The objective of the discussion paper was to inform business and community stakeholders of the nature of the reforms the government was considering and seek their views on issues affecting their further development and implementation and their likely impacts. The policy paper outlined the proposed reforms and no aspect of the proposal was finalised when the consultation began. It was made clear to the stakeholders that their views were sought to refine the proposed policy design and implementation. The consultation strategy and the relationship between the better regulation reform initiative and COAG's single national framework were also clarified for stakeholders.

The consultation period commenced with Minister Ludwig's release of the *Better Regulation of Agricultural and Veterinary Chemicals* policy discussion paper on 19 November 2010 and closed on 4 February 2011. The 11-week consultation period was provided to sufficiently cover any difficulties caused by the Christmas–New Year holiday period, through which many companies advised they ran a skeleton staff. The 11-week period also included a two-week extension in consideration of the extreme weather events of January 2011 that severely affected large parts of Queensland, northern New South Wales and Victoria.

The discussion paper was published on DAFF's website and stakeholders were informed by a joint media release by the Minister for Agriculture, Fisheries and Forestry and the Minister Assisting on Deregulation. It was also advertised on the APVMA's website and in its newsletters. Emails were sent directly to stakeholder representative bodies and more than 380 individual stakeholders who had registered interest in agvet chemical reform with the Primary Industries Standing Committee's (PISC's) Product Safety and Integrity Committee (PSIC). PSIC members, the APVMA board and members of its consultative committees were also contacted directly.

As the proposed reforms addressed complex subject matter, to further clarify the key issues, DAFF organised one-on-one meetings with key business and community stakeholder representative bodies—ACCORD (representing the consumer, cosmetic, hygiene and specialty products industry), Animal Health Alliance, Choice, CropLife

Australia, the National Farmers' Federation, the Plastics and Chemicals Industries Association, the Veterinary Manufacturers and Distributors Association and the World Wide Fund for Nature.

Relevant state and territory governments and Australian Government agencies were consulted to ensure that regulatory policies across jurisdictions were consistent and complementary.

Ninety-two submissions were made by organisations representing agricultural and veterinary chemicals manufacturers and distributors, chemical users, the environment and the community. Individuals and companies also made submissions. It is notable that 11 individuals made identical submissions based on the Choice submission.

Stakeholder submissions that were not marked confidential were published on DAFF's website shortly after they were lodged.

5.2 Consideration of stakeholder views

The primary area of consensus in the public submissions was that the effectiveness and efficiency of regulation should be improved. However, the chemical and agricultural industries expressed concerns about reforms that they perceive would increase costs while community groups expressed concerns about reforms that they perceived would not adequately protect health and the environment.

Specific areas of contention across the submissions related to the cost-recovered accelerated assessment process, the review and re-registration of existing chemicals, the role of the science panel and the advisory structures.

Stakeholders were invited to provide information to support views and to raise any additional issues and ideas not covered in the discussion paper. Stakeholder views on the proposed reforms are described below under the following headings, which were used in the discussion paper.

5.2.1 Implementing complete risk frameworks for agvet chemicals assessment and reviews

Stakeholders strongly supported the development and publishing of an overarching framework for agvet chemicals. They supported publishing decision-making methodologies, guidelines and standards for assessing applications. They also supported the concept of aligning the level of assessment for applications and reviews with the level of risk—provided the low- versus high-risk products were properly defined—but many expressed concerns about the practical implementation.

5.2.2 Assessment and registration of new chemicals

Stakeholders generally supported some registration assistance being provided for an application at no additional cost to the applicant. However, there was some concern among industry stakeholders about the potential for these measures to subsidise less sophisticated firms. Stakeholders supported an administrative check of applications restricted to completeness against application requirements; legislated time frames imposed for submission of additional data by applicants at the APVMA's request; extensions of time granted by mutual agreement; and removal of the requirement to assess efficacy or trade aspects of low-risk products.

There were mixed views on additional advice beyond initial pre-registration assistance being provided on a cost-recovered basis (there was some industry concern over the potential for measures to subsidise smaller firms); allowing no category changes at the applicant's request after lodgement of application (industry believed there was a need for flexibility to avoid unintended outcomes); and giving the APVMA the power to reject an application if it is deficient or requested data is not supplied in the required time frame (industry argued that flexibility was needed). There was strong opposition to the implementation of a cost-recovered accelerated assessment, as many argued that the focus should be on improving the normal channel.

5.2.3 Enhancing the agvet chemical review arrangement

Stakeholders supported maintaining the existing review process, enhanced by the inclusion of statutory time limits for provision of data. There was a strong divergence of views on implementing a systematic, risk-based re-registration process for all agvet chemicals. Some industry bodies also raised the need for improved data protection.

5.2.4 Using overseas data

Stakeholders supported using agvet chemical assessment undertaken by comparable overseas regulatory agencies. However, some industry stakeholders were concerned about using assessments from regulatory agencies using hazard-based systems.

There were mixed views on using the criteria of the Stockholm Convention on Persistent Organic Pollutants and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

5.2.5 Establishing an independent science panel

Stakeholders considered that the role for the panel suggested in the discussion paper was too administrative. Many suggested that the eminent group of scientists could play a role in developing risk frameworks.

5.2.6 Enhancing the provision of expert advice

Stakeholders generally agreed that the current advisory board is not adequate. A range of alternative models were suggested. For example, community groups suggested revamping the board to provide for greater community engagement.

5.2.7 Improving legal interaction with the APVMA

Stakeholders supported restricting the power of the Administrative Appeals Tribunal to stay decisions when human health or the environment is at serious risk.

5.2.8 Improving the APVMA's compliance enforcement regime

Stakeholders supported the provision of a contemporary, graduated enforcement regime.

5.3 Additional stakeholder views

Apart from the policy proposals canvassed in the discussion paper, stakeholders put forward some new ideas. Some industry stakeholders suggested that there should be fee

rebates where the APVMA does not meet statutory time frames, which would encourage the APVMA to meet time frame requirements. There was strong industry support for improved data protection, and for consequential changes to data protection resulting from other reforms.

Community stakeholders suggested that there needs to be a whole-of-government strategic policy on the sustainable use of pesticides in Australia. They also suggested transferring the levy collection task to DAFF, as it may reduce perceptions of the APVMA being beholden to industry.

Suggestions were made to include third-party appeal rights in the Agvet Code. Increased fees and levies for registrants to provide better funding for the APVMA was another suggestion that came from the community groups. They also proposed the publication of health and environmental safety data provided by registrants, assessments made by OCSEH and SEWPaC, and aggregated pesticide sales data in order to provide better access to this data. Community stakeholders urged the redirection of funding for more independent, public interest research and to encouraging pesticide-free farming, integrated pest management and organic farming.

Chemical user groups emphasised the need to address chemical access for minor use crops. They also expressed some concern about the 'off-label' use of chemicals.

Section 6 Conclusion

As a whole, the preferred reforms proposed in this regulation impact statement seek to improve both the efficiency and effectiveness of the Commonwealth regulation of agvet chemicals. The reforms would ensure a high level of transparency in relation to regulatory processes, thereby improving the consistency and predictability for business and community stakeholders. The reforms also seek to better align regulatory effort with risk, which would lead to more efficient outcomes for business and more effective outcomes for the community.

The implementation of a comprehensive risk framework would be a central feature of these reforms. This framework would provide greater transparency, inform more consistent and predictable assessment processes and contribute significantly to improving the overall quality of applications coming to the APVMA. In combination with other reforms to statutory time frames and data protection, the framework would provide a systematic approach to improving regulatory performance and outcomes.

It is anticipated that the overarching risk framework will be developed by the end of 2011 to make clear the high-level objectives and strategic guidance. Specific components of the risk framework would be finalised sequentially through 2012 and 2013. The benefits associated with the development of the risk framework are not expected to flow for at least some months after the publication of all components, as companies will need time to integrate their improved understanding of the regulatory requirements with their product development and application preparation procedures. Because of the long lead times associated with developing agvet chemicals, the benefits of this reform may not be fully realised for some years.

It is expected that this improved regulatory performance will lead to greater incentives for companies to bring innovative chemistry to Australia or to invest in the development of innovative chemistry to meet the needs of Australian agriculture and other users of agvet chemicals. This is critical at a time when agvet chemicals account for around 17

per cent of total farm costs and there is increasing pressure to improve the productivity of the agricultural sector to underpin food security while continuing to provide high human health and environmental outcomes.

At the same time, the reforms seek to provide the Australian community with a higher level of assurance that the chemicals registered for use continue to be safe and do not pose an undue risk to human health or the environment. To achieve this, the reforms include a systematic approach to identifying chemicals for review that enables greater scrutiny of existing registrations and approvals. The proposed system, which includes a process for re-registration of agvet chemicals, is risk-based and draws together information and data provided by chemical companies and other sources. This measure would introduce additional costs to approval holders and registrants, who under the existing system are not subject to re-registration requirements. The increased cost to the agvet chemical industry would, however, be outweighed by the benefits to the broader community through improvements to the chemical review program and greater confidence in the integrity of the NRS.

The revision of data protection provisions in relation to agvet chemical reviews would give data providers the opportunity to recoup the costs associated with developing or procuring data. This would provide them with an incentive to contribute information to the chemical review process and would reduce the likelihood of otherwise safe agvet chemicals being removed from the market because of a lack of access to data. While registrants of generic chemicals may be faced with higher costs to access data, improved arrangements for negotiating access to data would ensure that they have the opportunity to continue the registration if the APVMA is satisfied that the registration should be continued.

The inclusion of a systematic risk-based process for chemical review, combined with the business efficiency and transparency measures, provides the basis for a more sustainable regulatory system. The reformed system would be better able to adjust to the changing demands of business and the wider community over time. This systematic approach to regulatory reform also ensures that any adverse impacts on business arising from reforms in relation to re-registration of chemicals and ensuring better quality applications before proceeding to formal assessment are offset by the overall improvement to the regulatory environment.

As well as improving the efficiency of the agvet chemical industry’s engagement with the APVMA, the reforms would add to the functions that the APVMA is expected to perform. Accordingly, this reform package provides a balance of benefits for the agvet chemical industry and the community. In recognition of the broad benefits, the Commonwealth has committed $8.75 million to fund implementation of the reforms.

Further development of the detail of the proposed reform measures and detailed planning for their implementation will be undertaken in consultation with stakeholder representatives over the course of 2010–11 and 2011–12, with implementation expected to be substantially completed by 2013–14. DAFF will work with the APVMA and other agencies to make the necessary legislative, operational and governance changes to bring these reforms into effect. This will include the APVMA developing the necessary guidance material for applicants and registrants.

Section 7 Related issues

Parallel processes are being undertaken in regard to the following reforms:

- COAG's single national regulatory framework for the control of use of agvet chemicals after the point of retail sale
- implementation of COAG's 'early harvest' reforms for agvet chemicals, and
- non-legislative reforms to improve effectiveness and efficiency of the APVMA's regulatory processes, including governance and operational enhancements within the APVMA.

Section 8 Implementation and review

The Commonwealth has committed $8.75 million to fund the reforms.

Following government consideration and further consultation, an amendment Bill with transitional provisions would be developed for introduction in the spring 2011 parliamentary sittings. Implementation of the proposed legislative amendments is proposed to commence from 1 July 2012. Work is already underway on non-legislative reforms in measures group 1, as this is an important precursor to many of the other reforms, particularly measures group 2. It is anticipated that measures group 3 would be implemented promptly once the new legislation is in place.

Implementation of the risk framework measures would take place over a longer period. The risk framework documents, which will codify existing policies and procedures, would be developed by the APVMA and its regulatory partners OCSEH and SEWPaC, in consultation with stakeholders. It is anticipated that an overarching risk framework document would be developed by the end of 2011 to provide strategic guidance that will assist the development of specific components dealing with public health; occupational health, chemistry and manufacture, residues and trade, and the efficacy and safety components of the environmental component, which has already been developed. These components would be finalised sequentially through 2012 and 2013.

DAFF and the APVMA would commence monitoring the impacts of reforms from 2012 through their regular informal (approximately monthly) and formal (quarterly) executives meetings.