Australasian Compliance Institute

13 June, 2007

Regulatory Burdens – Primary Sector

Productivity Commission

PO Box 80

Belconnen ACT 2616

By email: regulatoryburdens@pc.gov.au

Attention Maggie Eibisch

Productivity Commission Annual Review of Regulatory Burdens on Business

This submission is provided by the Australasian Compliance Institute (ACI). The ACI is the peak industry body for the practice of compliance in Australasia. Our members are compliance professionals actively engaged in the private, professional services and Government sectors in Australia, New Zealand, Thailand and Hong Kong.

ACI welcomes and thanks you for the opportunity to provide comment in relation to the Productivity Commission's Annual Review of Regulatory Burdens on Business. We also appreciate the extension in time granted to make this submission which has allowed us to more broadly canvas the views of our membership regarding the potential compliance impacts of the proposals.

ACI supports the government's objectives to simplify and improve regulation. Our submission is directed toward achieving an outcome that both meets the government's policy agenda as well as providing an outcome that is both workable and effective for industry and provides a benefit to consumers. While this is the first year of a five year annual review of the regulatory burdens faced by business, ACI believes that as its membership broadens and given our policy focus upon the need to keep compliance costs to a minimum, that we will be making a submission to the Productivity Commission each year on some aspects of the annual review.

Our submission has been prepared by a ACI's special purpose Working Group comprising volunteers with a compliance role within Australia's Agricultural & Veterinary Chemicals industry.

Foundation Members

Australia's First Bank
PricewaterhouseCoopers
GWF George Weston Foods Limited
Ernst & Young Quality In Everything We Do
Zurich
nab
ANZ
Blake Dawson Waldron Lawyers
IAG Insurance Australia Group
KPMG
AMP

The Working Group's primary concerns facing the sector can be summarised within the following five points:

1. Cost to obtain registration of agricultural and veterinary chemical products.
2. Time required to obtain registration of agricultural and veterinary chemical products.
3. Cost to maintain registration of agricultural and veterinary chemical products.
4. Differences/inconsistencies between controls on use, supply and storage of agricultural and veterinary chemical products in individual States/Territories.
5. Differences/inconsistencies between requirements for registration of agricultural chemical products in Australia and overseas trading partners.

As an aside the Productivity Commission should note that the compliance community across all industry sectors is facing a shortage of adequately trained and skilled compliance resources available to meet the growing demand generated from the escalating regulatory burden. This demand is affecting not just the industry, but also the regulators who require resources to provide adequate supervision and oversight. It should be noted that any change in regulation, including changes designed to simplify or reduce the overall regulatory burden, impose an implementation load on already stretched compliance and other resources.

It is due to the above reasons that we believe that the government and regulators need to undertake careful planning, as the cost of these continuing changes are ultimately borne by the consumers that the legislation itself is aimed to protect.

In the implementation of any new or changed regulation consideration must be given to the potential impact on the cost of compliance and additional complexities the proposed changes may create. On the face of it, a proposal to reduce the immediate compliance cost or regulatory burdens on business may actually increase the complexity of the regulatory landscape, thus actually increasing the costs of compliance to the industry. We therefore request that further consultation occur with industry and the compliance profession by the respective government agencies prior to undertaking any regulatory reforms that may emerge following this review to ensure the goals of reduced compliance and regulation are achieved.

Conclusion

The ACI commends the government on its objectives of improving and simplifying the regulatory framework for business in Australia. However we believe that due to the observations discussed above, it is vital that the government take a holistic approach to the regulatory framework, including:

- Seeking a broad consultation, both across industry segments and also from both large and small scale operators, to ensure that there are no unintended consequences arising from the proposal;
- Consider more broadly the timing of other regulatory initiatives to ensure that business has the time to properly assess and implement the changes required to ensure an outcome commensurate with the government's objectives.

Response to Productivity Commission Annual Review of Regulatory Burdens on Business -- Primary Sector

Summary

Agricultural and veterinary chemical products are essential for protecting Australian primary industries from pests, diseases and weeds, including protection from exotic pests, diseases and weeds that may enter the country. Agricultural and veterinary chemical products also protect Australia's exports of primary produce by enabling compliance with trading partner quarantine requirements.

Supply and use of agricultural and veterinary chemicals in Australia requires that those products be first registered by the Australian Pesticides and Veterinary Medicines Authority. An effective registration system is considered to be essential in protecting consumers, the environment and international trade in Australian primary produce.

While an effective registration system is considered essential, the system should not impose burdens that prevent the introduction of new products that benefit Australian primary industries.

The current registration process for agricultural and veterinary chemical products imposes significant barriers on the introduction of new agricultural and veterinary chemical products. These barriers prevent new products being made available to Australian primary producers and foster registration of generic versions of existing products, even if those technologies are not optimal.

The barriers to the introduction of new agricultural and veterinary chemical products are:

1. Cost of registration of new agricultural and veterinary chemical products.
2. Time required to obtain registration of new agricultural and veterinary chemical products.
3. A data protection system that prevents data owners supporting use of proprietary data to obtain permits for use of products in minor use situations.
4. Differences in legislation between different states/territories inhibiting operations of both farming operations and industries that service those operations by supplying agricultural and veterinary chemical products and advice on their use.
5. Ineffective enforcement of regulatory requirements providing incentives for non-compliance and providing competitive advantage to those who choose to comply over those who comply.
6. Duplication of legislation covering agricultural and veterinary chemical products.
7. Differences in requirements for registration in Australia relative to overseas countries which results in increased costs for registration of products in Australia.

For Australian primary producers to gain full benefit of innovation in agricultural and veterinary chemical products, it is necessary to:

1. Provide protection for data submitted in support of permit applications so that data owners are safeguarded when supporting use of products for situations that do not justify investment in full registration.
2. Where full registration cannot normally be justified, enable conversion of permits to full registration after use has demonstrated no adverse effects and the product to be effective.
3. To encourage registration of new products, reduce the registration fee to that comparable with fees payable to notification of other industrial chemicals.
4. Recognize that new technologies can benefit Australia as a whole, including the environment and consumers. As a result, funding for APVMA should include public funds rather than being solely dependent on fees and levies paid by registrants.
5. Reduce the cost of registration by allowing APVMA to accept and rely on reviews conducted by other regulatory authorities.
6. Reduce the cost of data development by use of a more flexible GLP system for generating residue data and greater use of product groupings when generating efficacy and crop safety data.
7. Reduce the time required to registration by eliminating the need for agricultural chemicals used only in the workplace (e.g. on farms) to require Poison Scheduling.
8. Reduce the time required to obtain registration by greater reliance on outsourced expertise for evaluations.
9. Reduce confusion and the potential for non-compliance by development of a unified system across all States and Territories for the control of use of agricultural and veterinary chemical products.
10. Establish an independent audit or review panel to review APVMA decisions thereby overcoming the substantial cost in challenging APVMA decisions through the Administrative Appeals Tribunal.

Response to Productivity Commission Annual Review of Regulatory Burdens on Business -- Primary Sector

Part 1 – Industry Background

The production of primary produce in Australia, as it does in other countries, is dependent upon effective methods for the control of pests, diseases and weeds. Such controls include chemicals as well as non-chemical means.

Chemicals used to protect crops and animals are known as agricultural and veterinary chemical products.

Agricultural and veterinary chemical products include chemicals used to control insects, diseases in crops, diseases in animals, undesirable plants as well as including disinfectants and sanitisers used in dairies, animal houses, vaccines used in animals, plant growth regulators, etc. Agricultural and veterinary chemical products may be made from synthetic chemicals, naturally occurring chemicals, analogues of naturally occurring chemicals, microbial agents (e.g. bacteria, viruses), products derived from microbial agents and include products of gene technology (e.g. genetically modified plants expressing traits for the control of pests or chemical substances produced from generically modified organisms).

New active constituents and new products provide Australian producers with the latest technology in protecting agricultural commodities (including eggs, meat, milk, timber, fruits, vegetables, etc) against developing pests, diseases and weeds as well as combating resistance to existing technologies. Such innovations can include products/technology developed in Australia as well as technology imported from outside Australia. These innovations help protect exports that have been valued by the Australian Bureau of Agricultural and Resource Economics at $27.2 billion in 2007-08.

While Australian exports of agricultural commodities are significant, Australia is a minor user of agricultural and veterinary chemical products. Estimates of the proportion of the global usage of agricultural and veterinary chemicals vary but a commonly quoted figure is that Australia accounts for approximately 2% of global use of agricultural and veterinary chemical products. Although the small size of the market does not justify investing the large amounts of money necessary for development of new agricultural and veterinary chemical products (that can exceed $75 million), it is accepted that for new substances the "safety" of products must be demonstrated and therefore the general requirements for approval of newly synthesised active constituents must be met to ensure the safety of users, bystanders, the environment and international trade.

The importance of agricultural and veterinary chemicals to Australian primary industry

Agricultural and veterinary chemicals include natural and synthetic remedies for pests and diseases affecting crops and animals as well as weeds that compete with crops. The supply and use of agricultural and chemical products is regulated by the *Agricultural and Veterinary Chemicals Code Act 1994* plus State and Territory legislation and regulations.

In addition to use in protecting crops and animals from pests and diseases and weeds, agricultural and veterinary chemicals have an important role in protecting Australian agriculture from exotic pests including through eradication of exotic pests detected in Australia and protecting international trading in Australian commodities by ensuring commodities comply with quarantine requirements imposed by Australia's trading partners.

Ensuring the safety of agricultural and veterinary chemical products

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is given the responsibility for ensuring the safety of new agricultural and veterinary chemical products to users, bystanders, the environment and international trade. This responsibility is discharged by registration of agricultural and veterinary chemical products in accordance with the *Agricultural and Veterinary Chemicals Code Act 1994*.

After registration, storage, distribution and use of agricultural and veterinary chemicals in Australia is impacted by a large array of legislation and other regulatory instruments. Legislation and regulatory instruments include:

- Occupational health and safety legislation,
- Transport regulations,
- State and Territory poisons and health laws,
- Environmental laws (both State and Federal), as well as
- Laws related to weights and measures, for example fair trading
- Various codes of practice/conduct.

Making new agricultural and veterinary chemicals available to primary producers

Agricultural and veterinary chemicals can be supplied in Australia by the:

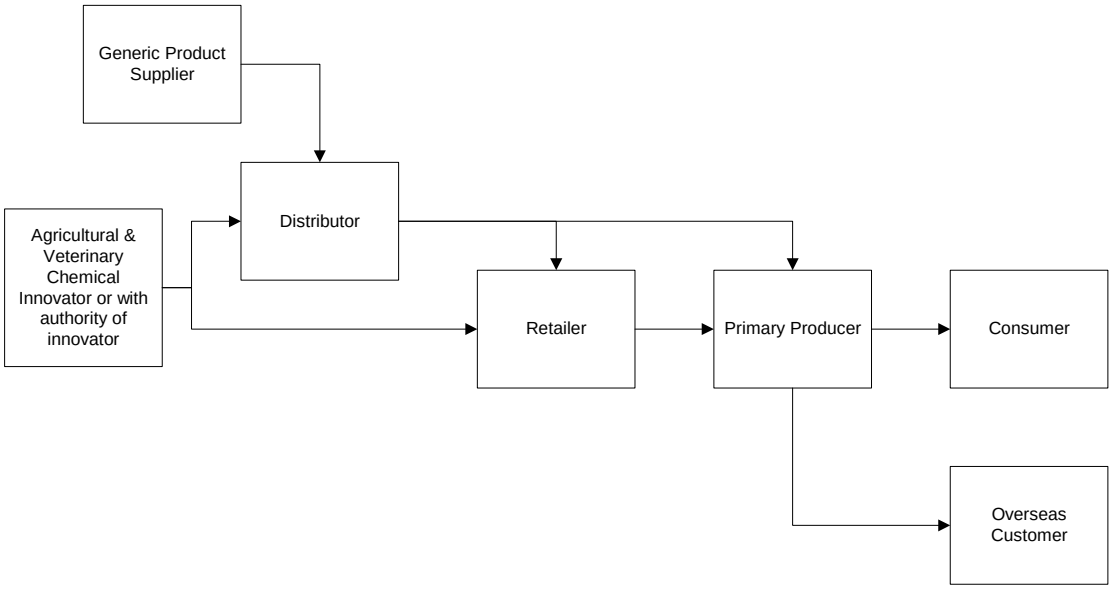
- "Innovator" (or discoverer) of the material who registers the product with the APVMA,
- Another organisation that registers a novel material on behalf of the innovator,
- Another organisation that registers a similar product to that registered by the innovator or another product based on the active constituent used in the innovators product, i.e. supplies a generic equivalent of the pioneer product, or
- Any entity that supplies its product into Australia without registration, that is supplies the product illegally.

Assuming the product is registered, it is normal for the registrant to either:

- Sell the product through a distributor to various agricultural and/or veterinary chemical retailers, or
- Supply the product directly to the agricultural and/or veterinary chemical retailers.

The product is then supplied by retailers to primary producers who use the product.

This common distribution chain is illustrated in the following diagram. However, it needs to be noted that there are instances of companies supplying directly to end users and through other channels.



The need for an effective regulatory system to control agricultural and veterinary chemical products

It is critical that Australia have an effective regulatory system that protects users, bystanders, the environment and international trade of commodities/produce produced in Australia.

An effective regulatory system is critical. The community is concerned with "chemicals" in foods and the environment as a whole, as evidenced in the rapid adoption in developed countries of organically produced commodities, including "natural" products for cleaning and for use as cosmetics.

Without an effective regulatory system, community concerns could significantly impact upon acceptance of commodities and produce grown using "conventional" methods (which include the use of agricultural and veterinary chemicals).

This submission to the Productivity Commission Enquiry into the Regulatory Burdens on the Primary Sector accepts and supports the need for a strong and effective regulatory system for control of agricultural and veterinary chemicals but, at the same time, highlights certain issues within the current system for the regulation of agricultural and veterinary chemicals that adversely impact the use of those chemicals and primary production.

Part 2 – The Regulatory System as it Currently Operates

Approval and registration of active constituents and chemical products involves:

1. Generation of data for use in demonstrating the product can be used without undue risk to people, target crops/animals, the environment and international trade plus data to demonstrate the product, when used according to the proposed directions for use, will be effective.
2. Submission of the data along with the appropriate APVMA fee to APVMA.
3. The submission is "screened" by APVMA for completeness. It is not uncommon for APVMA to request clarification or additional information during the screening process.
4. Once screening is completed, the application enters "evaluation". In the evaluation phase, the documents may be reviewed by relevant personnel within APVMA (mainly Chemistry data and Residues information) with other information being sent for external review, e.g. toxicology is evaluated by the Office of Chemical Safety, environmental effects are assessed by the Department of Environment and Heritage while efficacy data are often assessed by relevant specialists in State and Territory Departments of Primary Industries. Frequently, additional questions are asked of the applicant during the evaluation phase.
5. During evaluation, APVMA determines whether the product/substance can be approved/registered or not. If an active constituent is determined to be acceptable for approval, the applicant is notified that the substance has been approved. If a chemical product is suitable for registration, the applicant is requested to submit label artwork.
6. Label artwork is assessed by APVMA during "finalisation" of the registration to ensure the label complies with relevant requirements, including those of the Standard for Uniform Scheduling of Drugs and Poisons but does not include compliance with Dangerous Goods labelling requirements.
7. Once the label artwork has been accepted by APVMA, a certificate of registration is sent by APVMA to the applicant confirming the product is registered and can be sold.
8. Each year, the applicant/registrant must pay registration fees and levies to APVMA in accordance with the requirements of the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*. Failure to pay the levy will result in the product registration being cancelled.

After initial registration of a new product, changes to the registration can include:

a) Addition of new uses to the label.
b) Variations to the way the product is used/applied.
c) Removal of uses (e.g. if subsequent information determines the product is not effective or causes damage in certain situations)
d) Changes to the particulars of registration, e.g. company name, product name, location at which product is formulated/manufactured.

In addition, others may copy the label with a similar product to register a generic equivalent or "me-too" product.

In addition to registration of new products, it is necessary to obtain temporary approvals from APVMA to evaluate new products and for products to be used for purposes other than those for which they are registered.

While small scale trials are covered by a general permit issued by APVMA (Permit 7250), larger scale uses requires submission of an application that may require the submission of essentially the same data as that required for registration of the product in the same situation.

Who funds registration of agricultural and veterinary chemical products

Currently the agricultural and veterinary chemical industry carries the burden for funding registration of agricultural and veterinary chemical products through cost recovery fees and levies imposed in the national registration scheme.

The costs associated with registering a new agricultural or veterinary chemical product include:

a) Cost of studies to confirm safety of the product.
b) Cost of studies to confirm the product is efficacious and can be used in the proposed situation.
c) Registration fees
d) Annual levies payable to maintain the registration.
e) Cost of compliance with regulatory requirements, including cost of attending to APVMA required audits (e.g. GMP audits), establishing systems for recording and maintaining APVMA required information.

According to the APVMA[1], 49% of applications for 2005/2006 were supported by additional information which the APVMA did not request, i.e. approximately half of all submissions require the applicants to submit additional data. It would appear that this additional information has been provided in circumstances where the APVMA has refused registration or severely restricted the use of a new chemical product. The APVMA is now proposing to levy additional fees in those circumstances to cover additional screening or the re-screening of evaluations already performed.

[1] See APVMA Costs Recovery Impact Statement on the Method for Working out the Fee for Applications where Additional Information is Submitted Voluntarily, May 2007.

Part 3 – Areas of Concern

No attempt is made in this submission to list the large number of regulatory instruments affecting the supply of agricultural and veterinary chemicals in Australia. Instead, this document concentrates on deficiencies in the current system, and their consequences.

The deficiencies in the current system can:

1. Prevent new technologies being made available to Australian producers or retard their introduction into Australia.
2. Result in higher costs for required agricultural and veterinary chemicals made available to Australian primary producers.

The key issues are:

1. Registration of new agricultural and veterinary chemical products and new uses for agricultural and veterinary chemicals is expensive and too time consuming resulting in smaller enterprises not being able to afford to introduce novel products into the Australian market, whether those technologies are developed in Australia or overseas.
2. A data protection system that prevents innovators fully evaluating their products before registration.
3. Differences in State and Territory laws controlling use and the ability to make recommendations in relation to the use of agricultural and veterinary chemical products.
4. Duplication of legislation covering agricultural and veterinary chemical products.
5. Ineffective enforcement and/or inconsistent enforcement of regulations controlling the supply and use of agricultural and veterinary chemical products.
6. The effectiveness of ACCC authorised codes of conduct in achieving their objectives.
7. Compatibility of Australian Requirements with overseas countries.

1. Registration of new agricultural and veterinary chemical products.

Registration of new products containing new/existing active constituents

Registration of new agricultural and veterinary chemical products based on existing active constituents suffers from considerable delays and expense. It should be noted that veterinary chemical products, other than ectoparasiticides, do not require approval of the "active constituent" if the active component conforms to standards specified in accepted pharmacopoeia.

Registration of a new product containing an approved active constituent for use in a crop in which the specified active constituent is not already used requires payment of application fee to APVMA of $31,750 and involves an evaluation timeframe of 15 months, i.e. a minimum of two and probably three seasons from the time the application is submitted until registration is granted. This fee is payable and the timeframe applies even if the active constituent is used in other crops/situations.

Such costs and delays discourage the development of new products for new uses, including finding solutions to problems arising from changing market conditions, e for example, needs arsing from cancellation of registrations for existing products, to address consumer concerns about currently used products, overseas trading partner actions in relation to specific chemical products and new crops and pests/situations, especially where the "opportunity" is relatively small.

Example: Agricultural chemicals for use in commercial forestry

Forestry is not considered to be a "minor" crop and operates in areas that are commonly considered to be environmentally sensitive. However, establishing a new plantation requires the same care as required for the establishment of any other crop including protection from competition from weeds and damage from pests and diseases. Mature forests can be subject to pest attack and may require the use of chemical products to control those pests.

Due to the low total usage of agricultural chemicals in forestry (0.7% of total agricultural chemical usage in Australia), agricultural chemical companies are reluctant to register new products used in forestry, even if these products are registered for use in other situations. Consequently, forestry relies heavily on APVMA issuing permits to allow the use of products. Currently forestry accounts for approximately 6% of total permits issued by the APVMA.

The cost and delays in obtaining registration for agricultural chemical products effectively prevents the Australian forestry industry from implementing the Forestry Stewardship Council (FSC) Pesticides Policy that states:

> *The FSC Criteria include three core elements:*
> *a) The identification and avoidance of 'highly hazardous' pesticides;*
> *b) Promotion of 'non-chemical' methods of pest management as an element of an integrated pest management strategy; and,*
> *c) Appropriate use of the pesticides that are used.*

The high costs and long timelines required for registration mean that Australian forestry operators must rely on existing chemical products even if lower risk alternatives are available elsewhere. Reliance on such products makes implementation of integrated pest management strategies difficult due to older and more hazardous products often being more disruptive to beneficial organisms that could help promote sustainable control of pests.

As a minor user of agricultural chemicals, forestry does not obtain much support from agricultural chemical companies. Consequently forestry companies are required to apply for their own permits for the use of existing agricultural chemical products, for example, Timbercorp has obtained Permit 9215 for the use of Fusilade (a grass herbicide) in its forests. Such permits are issued for a set time period, for example, Permit 9215 was issued on 12 February 2007 and will expire on 30 June 2009.

The preparation of permits, which must be done by the applicant (in this case Timbercorp) is a time consuming process and the issue of permits can be a

lengthy process, with processing time at APVMA for forestry permits being 3-11 months from application to issue of a permit. Depending on the type of permit, the APVMA fee varies from $320 to potentially thousands of dollars (if the permit application requires technical assessment).

Failure to meet the FSC standard will result in Australian forestry corporations being unable to trade with an increasing number of customers who make FSC certification a condition of purchase, eg Ikea, Home Depot and government procurement contracts for the Netherlands and Denmark.

Costs of Registration of New Products

Upfront Fees: The fees and levies paid are considerably higher than those paid in relation to industrial chemicals, which must also demonstrate safety to users, bystanders and the environment.

Cost Comparisons with Other Industries/Regulatory Authorities: Ignoring the cost of studies, the APVMA requires payment of $48,860 at the time an application for approval of a new active constituent and new product containing that active constituent is submitted to the APVMA. This can be contrasted with the fee payable to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for notification of the same chemical substance that requires payment of $14,418 which can be further reduced by rebates where the application is supported by an assessment report from a national authority of an OECD member country (especially Canada).

Cost of approval and registration by APVMA can also be contrasted with approval to use new materials in foods. The cost of obtaining approval for a new food ingredient is determined by the amount of time required to assess the application. Food Standards Australia New Zealand quotes fees as likely to vary from $18,700-$155,000. Consequently, obtaining approval for a new ingredient added directly into food may cost more or less than obtaining approval and registration for a new agricultural or veterinary chemical product that at the time of consumption maybe totally absent from the food in question. However, it needs to be noted that time costing is not considered to be an efficient method for charging as it can "reward" inefficiencies.

.

Example: Octenol as an attractant for use in mosquito traps
Octenol is a fragrance material used in toiletries, perfumes and soaps. It was listed on the Australian Inventory of Chemical Substances prior to the application being submitted to the APVMA for registration as an attractant for use in mosquito traps. Even though the product could be legally used in toiletries and perfumes, it was still subject to full evaluation by the APVMA, including payment of the full registration fee, before it could be legally used as an attractant in mosquito traps. Registration of the first product containing octenol took approximately 2 years from the date of the submission.

In summary, an application for registration of a new agricultural chemical product based on a new active constituent requires payment of $48,060 to APVMA. Notification of that same chemical substance to NICNAS requires payment of $14,418 while approval to use the same chemical as a direct additive into food might vary from $18,700-$155,000, depending on the complexity of the application.

While fees are important, the real cost for registration of new agricultural and veterinary chemical products includes:

1. Fees payable to the APVMA upon application plus
2. The cost of being excluded from the market while registration is obtained.

Data Costs: The small usage of products in Australia does not justify the massive costs involved in generating all the data commonly required for registration of new agricultural and veterinary chemical products. Consequently, a new chemical substance would rarely be developed only for the Australian market. As a result, the investment in generating basic data in support of approval of a new active constituent would normally be shared over a broad range of countries.

Studies to confirm the safety of the active constituent are generally conducted to satisfy the requirements for registration in numerous countries and are essentially similar. However, there are situations where the requirements imposed in Australia exceed those in other countries.

Similarly, the requirement to register an agricultural or veterinary chemical product can be more expensive than that for the same product when used as an industrial chemical or as an additive in food. As an example, the *Industrial Chemicals (Notification and Assessment) Act 1989* makes provision for polymers of low concern to be exempted from the requirements for data known not to be applicable. There are no similar exemptions under the *Agricultural and Veterinary Chemicals Code Act 1994* although modular categories can be used in an attempt to submit reduced data sets, although this has not normally been successful.

It is assumed the 49% of applications referred to in the APVMA Costs Recovery Impact Statement on the Method for Working out the Fee for Applications where Additional Information is Submitted Voluntarily dated May 2007 refers to situations where applicants have attempted to submit lesser data sets than specified in the guidelines.

The cost of generating data can be substantial and can be a disincentive to companies to obtain registration even if they know their products are effective and can be used with confidence. With newer technologies, for which there are no established testing methods to confirm efficacy, the normal delays in registration can be further compounded by the requirement to negotiate suitable testing methods with APVMA. This problem is particularly acute in relation to animal health remedies.

Example: Australian company decides not to register new products

One small Australian animal health products company has advised it currently has four products it would like to sell in Australia. However, due to cost of registration, the company has decided not to register those products in Australia.

Additional Fees from 1 July 2007

The imposition of additional fees by the APVMA fails to address deficiencies in the manner in which the APVMA currently determines applications including the decisions it makes to request or not request relevant information. The applicant may find it necessary to submit additional data that the applicant does not believe is necessary in an attempt to convince APVMA to approve and application. The imposition of additional fees, as proposed, does not address the underlying organisational deficiencies that result in almost half of all applications finding it necessary to submit additional information.

Time Frames in the Regulatory System and their Effect: The evaluation timeframe for an application, as specified in the *Agricultural and Veterinary Chemicals Code Regulations 1995*, for a new active constituent with new chemical product is 15 months. This compares with 90 days for a new industrial chemical.

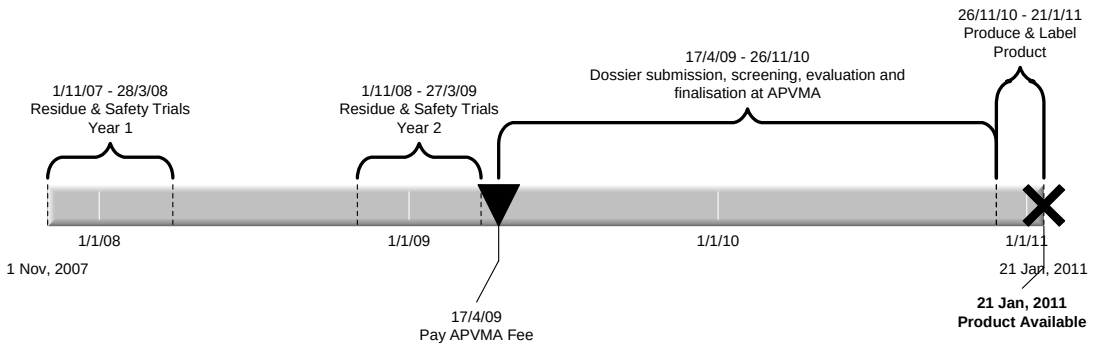
In addition to the 15 months evaluation timeframe, there is additional time required for "screening" the application before it enters evaluation and further time required for finalisation of the application after evaluation has been completed. The 15 month time frame is suspended each time APVMA asks for additional information. Consequently, the time to obtain approval and registration of a new active constituent and a product containing that new active constituent can be more than 18 months.

Due to the seasonality of most agricultural endeavours, an 18 month time frame commonly equates to 3 seasons. This is because product can not be supplied into the market until it has been packaged and labelled and it is not possible to print labels until APVMA has approved those labels.

A small to medium sized business is unlikely to invest in obtaining stocks of ingredients, packaging, etc. until it knows the product will be registered. It may require a number of months after registration is granted for ingredients to be available for manufacture of the product and for packaging and labelling to be available.

In addition to the 2-3 season delay in obtaining registration after an application is submitted to APVMA, it may also be necessary to generate efficacy data and residue data over at least two seasons before the application is submitted.

The following chart gives a timeline for development and registration of a product used in summer months:



The above timeline shows:

1. A need to pay for efficacy and residue studies in the first 2 years.
2. At the time of application, the APVMA fee must be submitted.
3. A realistic period for registration that results in registration being granted at about the start of the use period for the product 4 years after product development started.
4. An extremely optimistic period for production given that most label printers and other suppliers are closed over the Christmas/New Year period.
5. Availability of the product at the end of the fourth season after development of the product started.

The impact of this is a significant negative cash flow for the four years during the application period. These significant negative cash flows cannot be sustained by most small to medium sized businesses. The costs for this approval process to business can be further increased if the capital required needs to be secured from external borrowings.

Rather than incur such costs, it is more common for Australian small and medium sized businesses to introduce generic equivalent of already available products that, while helping reduce the price of such generic products, does not provide to Australian primary producers the latest technology available to their competitors in other markets.

Example: New products available overseas but not in Australia

Antibiotics cannot be used in Australia or the EU as growth promotants for livestock. Alternatives to antibiotics have been developed in the EU. These alternatives are not available in Australia due to the cost of registering them for use in a the relatively small Australian market.

Consequently, Australian producers are placed at a competitive disadvantage relative to their European competitors.

Maintaining registrations of agricultural and a chemical products

Currently the annual levy payable to APVMA for each registered product is:

1. 0.8% of disposals up to $1 million.
2. 0.45% for disposals greater than $1 million up to $5 million.
3. 0.3% for disposals greater than $5 million.

A company selling $4,999,999 worth of agricultural or veterinary chemicals in Australia is required to pay $26,000 in levies to the APVMA each year. In contrast, if that company was selling the same value of industrial chemicals, the annual registration fee payable to NICNAS would be $1466.

The cost of such fees is a disincentive to investing in developing and marketing new technologies to be used in Australian primary production. Consequently, companies may be tempted to avoid such costs by selling unregistered products.

Example: Neem-based products used in agriculture

Neem is a plant derivative that has a broad range of uses including control of insect pests. There are no neem-based products registered for use on food crops in Australia. Due to the well-known effects of neem, some agricultural producers are known to use neem-based products as pesticides, irrespective of whether the supplier recommends such use or not.

The example of the use of neem due to its well-known characteristics does not suggest that such products are improperly recommended. However, there are other situations where products are sold without registration and it is all clear that registration should have been obtained prior to making the products available for sale.

The high cost of registration and annual registration levies provides significant incentive for companies to seek ways to avoid registration and, as a result avoid scrutiny by a competent authority in relation to safety of their products.

Use of unauthorised products may place into question Australia's domestic and international reputation as a producer of clean green food and agricultural produce.

Conflict between APVMA and Overseas Requirements

Certain countries require a document called a "Certificate of Free Sale" (for example the United Arab Emirates) before the product can be registered in those countries. The APVMA will only issue this Certificate when a product has been registered for sale in Australia. Where a product does not require registration in Australia a Certificate of Free Sale will not be issued, even if the product requires registration in other countries. This prevents Australian innovations being exported to those countries for which the provision of the Certificate of Free Sale is mandatory.

Some Australian innovators have stated they are considering moving outside Australia to enable them to be able to sell their products in reduced timeframes. As a result, products may not be made available for use in Australia. This can place Australian primary producers at a competitive disadvantage to their overseas competitors.

Differences in definitions of terms such as "genetically modified" can result Australian products not being acceptable for use.

Example: New vaccines for use in protecting animals from diseases

New technologies include the use of genetically modified organisms to produce new products. In the pharmaceutical industry, products such as antibiotics are commonly produced using genetically modified organisms. Similarly, the production of vaccines can be significantly enhanced by use of genetically modified organisms.

While in other countries, vaccines produced using genetically modified organisms are not classified as being genetically modified unless they contain modified DNA/RNA, in Australia the use of genetically modified organisms to produce such

vaccines results in those vaccines being declared as products of gene technology. This has significant implications on their use as food producers frequently need to disclose whether products of gene technology has been used in the production of foods destined for export, e.g. meet from animals treated with vaccines that have been classified as products of gene technology in Australia.

As the vaccines are classified in Australian as being products of gene technology, their use precludes export of products derived from animals treated with the vaccines being exported to certain countries.

2. New Technologies – the Missing Benefit

The latest technologies include "safer" substances.

Safer or reduced risk compounds are promoted by regulators in other countries due to potential benefits in relation to human health, the environment and international trade. Such countries (as New Zealand and the USA) have introduced programmes to encourage the development of reduced risk products. There is no such system operating for agricultural and veterinary chemical products in Australia; even though one does exist in Australia for certain industrial chemicals.

The unavailability of reduced risk classifications for registrations effectively prevents smaller companies from registering innovations designed to satisfy the need for low risk products or products more acceptable to the general community relative to currently registered products. Such products are normally developed by smaller companies which do not normally have the high "hurdle rates" required in larger, multinational companies to justify development of new products. As previously discussed, the smaller companies are often unable to bear the cost of registration in Australia, and therefore it is uneconomical to bring these products to market.

3. Data Protection – A further disincentive for suppliers.

The lack of data protection given to proprietary information submitted in support of permits can prevent agricultural and veterinary chemical suppliers supporting permit applications.

While amendments to the *Agricultural and Veterinary Chemicals Code Act 1994* have resulted in data protection being provided for data submitted in support of product registration, data submitted in support of permits is not given any protection. Consequently, where industries such as forestry and minor crops rely on permits, they can find companies unwilling to support permit applications if it requires those companies to submit proprietary data. In some cases, agricultural producer organisations have submitted their own data to obtain permits but have lost competitive advantage in having incurred the cost of developing those data and then making it freely available to competitors through loss of data protection once those data have been submitted to APVMA.

Example: Timbercorp support for use of Terbuthylazine in Australian forestry

Timbercorp developed intellectual property that related to significant commercial advantage in the use of terbuthylazine in forestry. In so doing, the benefits were "shared" with Timbercorp's competitors.

It should be noted that while terbuthylazine is an approved active, there are no registered products available in Australia containing this approved active constituent.

4. Differences/inconsistencies in laws governing the use of agricultural and veterinary chemicals between different States and Territories.

As Australian primary production moves from family-owned farms to corporate farming and with large nationwide agricultural and veterinary chemical distribution organisations (for example Elders and Landmark) the differences in legislation between different States and Territories becomes pronounced.

The distribution and use of agricultural and veterinary chemicals in Australia is regulated under numerous different laws including:

1. The Commonwealth *Agricultural and Veterinary Chemicals Code Act 1994*.
2. State/Territory agricultural chemical/pesticide laws.
3. State/Territory poisons laws.
4. State/Territory occupational health and safety laws
5. Federal environmental protection laws.
6. State/Territory environment or protection laws.
7. The Australian Dangerous Goods Code.
8. Federal Transport of Dangerous Goods laws
9. State/Territory transport of dangerous goods laws.
10. Food Standards Code
11. State/Territory food laws
12. Other miscellaneous laws that make impact specific situations.

For example, there are 14 pieces of legislation covering road transportation of dangerous goods. While differences can often be minor they cause administrative difficulties in the distribution of chemical products. Any organisation operating across State/Territory borders must develop policies that cover all the areas in which it operates. Development of such policies is complicated by trying to define minimum acceptable standards for staff in the use or recommendation of agricultural and veterinary chemicals. To ensure compliance, organisations that operate across State/Territory borders often adopt the most stringent requirements. Adopting such a conservative approach can place them at a disadvantage in some areas relative to competitors who only operate in those specific areas.

As a result, large organisations that can bring economies of scale and new technologies to Australian primary production can be dissuaded from doing so due to the plethora of regulations that must be navigated to operate across Australia.

Example: Recommendation of agricultural and veterinary chemical products

Elders and Landmark provide expert advice to their primary producer customers through a network of qualified agronomists. Both companies operate Australia-wide.

All Australian agricultural chemical product labels state that it is illegal to use the product for any purpose other than for which it is registered. However, in Victoria, the *Agricultural and Veterinary Chemicals (Control of Use) Act 1992* permits the use of registered products at up to the maximum label rate on any crop provided that residues do not exceed permissible levels. In contrast, the *Pesticide Act 1999* in New South Wales prohibits the use of any pesticide other than in accordance with an issued permit or directions provided on the approved label for the product. Consequently, a farmer on the Victorian side of the Murray River may be able to control a pest using a product that is not registered for that specific purpose whereas the same farmer is not permitted to do so on the New South Wales side of the Murray River. Consequently, farming operations operating across borders need to consider permissible use within the State/Territories in which they operate when ordering agricultural and veterinary chemicals.

The imposition of national corporate policies on advisers can result in advisers not being permitted to provide advice to their clients that may appropriate in some states/territories but not in others.

On a smaller scale those distributors and their customers carrying on business in state border areas need to be aware that differing legislation may affect the manner in which they use a chemical product on the one property. Failure to do so may result in the distributor and or primary producer being liable for fines or other enforcement penalties where inadvertent breaches occur.

5. Duplication of legislation covering agricultural and veterinary chemical products.

Agricultural veterinary chemical products used in primary production are covered by numerous pieces of legislation. The legislation is administered by different agencies and can vary from State to State.

The use of agricultural and veterinary chemicals is controlled by:

1. APVMA registration requirements.
2. Occupational health and safety laws.
3. Environmental laws.
4. Licensing/accreditation laws.
5. Other miscellaneous pieces of legislation.

These federal and state legislative requirements can be confusing and inconsistent. Many national organisations can be subject to up to 6 separate pieces of legislation (more if regulations are included) dealing with one specific area. While the spirit of the legislation may be similar there can be intricate differences (for example record

keeping requirements) which result in each Act/regulation requiring individual consideration.

Keeping up to date with requirements is time-consuming and can require expert legal guidance.

There are significant risks in failing to remain up to date with legislative requirements and/or for misinterpreting some of the requirements. The rate of regulatory change has increased the risk that most organisations will fail to comply at some point.

Example: New South Wales legislation.

A pesticide label must be registered by the APVMA before the product can be sold in New South Wales. The label includes elements from the Standard for Uniform Scheduling of Drugs and Poisons (administered in NSW by NSW Health), workplace safety considerations (administered by WorkCover Authority of NSW), environmental effects (administered by NSW Department of Environment and Climate Change) as well as use legislation, weights and measures legislation, etc.

There is often conflict between the APVMA approved label and workplace chemical requirements required by the WorkCover Authority in New South Wales. This places an undue burden on users to comply with the requirements of the label, which is a requirement under the Pesticide Act 1999 and the Occupational Health and Safety aspects required by WorkCover NSW.

6. Enforcement of regulations controlling supply of agricultural and veterinary chemical products.

There are numerous examples of products that should be registered being sold without registration. These include:

- Timber treatments sold as paints or surface coatings.
- Agricultural chemical products sold as plant nutrients.
- Veterinary chemical products sold as animal nutrients (without claims).
- Agricultural chemical products sold as agricultural chemical products but without being registered.

Organisations that comply with registration requirements are subjected to high costs which include:

1. Generating data to satisfy registration requirements
2. Application fees payable to the regulator (APVMA).
3. Annual fees/leview payable to the APVMA.
4. Cost of compliance programs such as the APVMA Quality Assurance Scheme for active constituent used in agricultural chemical products.

In contrast, companies that do not obtain registration avoid these significant costs and therefore gain a competitive advantage over those companies that have invested time and money in complying with regulatory requirements.

Example: Octenol for use in attracting mosquitoes

One company has invested in obtaining registration of an octenol based mosquito attractant. Having paid fees for registration and being required to continue to pay ongoing levies, the company finds it is competing against a range of similar products supplied without registration. Despite complaints having been referred to the APVMA, those unregistered products continue to be made available in Australia.

As a result of unregistered products being made available in Australia, other companies with reduced risk technologies for use in a variety of situations have advised they will not register their products in Australia until their investment in complying with Australian regulatory requirements can be protected. This denies Australian primary producers and consumers with reduced risk options available to consumers and primary producers in other countries.

7. ACCC authorised code of conduct - AgSafe.

The ACCC has authorised a code of conduct that enables organisations supplying agricultural and veterinary chemical products to have sanctions imposed on them if they do not comply with the industry code of conduct for storage of such products.

There is a need for effective product stewardship that includes safe storage and handling of hazardous and dangerous chemicals. However, the current code of conduct does not adequately address this need. In particular, it is generally believed that sanctions against disreputable organisations will not be effective as such organisations are likely to be able to source product for supply from alternative sources.

Imposition of sanctions is only effective against the more reputable organisations. Consequently, the Code of Conduct administered by AgSafe, like registration, is a cost imposed on more reputable organisations while having minimal impact on organisations that choose to ignore registration or Code of Conduct requirements.

8. Compatibility of Australian requirements with overseas countries.

Australia is a minor user of agricultural and veterinary chemical products globally. However, those products are important in the production of agricultural commodities that are consumed within Australia and supplied to overseas markets.

The APVMA ensures that residues in commodities treated with registered agricultural and veterinary chemical products do not interfere with international trade through assessment of residue data. This is to be commended.

While APVMA ensures compliance with overseas residue requirements, APVMA also makes demands that go beyond requirements made in other countries. This can significantly impact availability of agricultural and veterinary chemical products in Australia.

Of significant concern is the Quality Assurance Scheme for active constituents used in agricultural chemical products.

The APVMA requires that the identity of the manufacturing facility that produces an active constituent be disclosed in documentation supplied to the registrant of a formulated product.

Active constituents may be supplied by a large overseas manufacturer to an overseas formulator who prepares product for distribution globally. The need to track the individual batch of active constituent used in the preparation of a formulated products supplied into Australia imposes costs on that formulator and, where product is formulated overseas, may not fit with procedures acceptable to other regulatory authorities (e.g. EU, USA).

In contrast with the Australian requirements, overseas authorities generally require that the active constituent come from an approved source and be suitable for purpose. In the case of materials sourced from Chinese and Indian suppliers, it is common practice for companies that supply those active constituents into Australia either as the active constituent or in formulated products, to analyse the active constituents and to issue their own certificate of analysis/batch confirmation. In some situations, active constituents from a number of factories may be used in the production of a single batch of formulated product in which case, the formulator would issue a certificate of analysis for the blended batch. This might occur if the "formulator" produces their own active constituent at a number of different manufacturing sites.

The requirement to segregate batches for Australia is a disincentive to companies supplying active constituents into Australia to supply those active constituents for use in Australia.

While the Australian requirement for residue data to be generated under Good Laboratory Practice (GLP) is similar to that in other developed countries, its implementation is different to those in other countries. In particular, the Australian system requires that data be generated, including field applications of products, be conducted by NATA registered facilities. There are few NATA approved facilities for generating residue data.

In contrast with Australian requirements, the USA requires that studies comply with GLP requirements. Furthermore, in submitting an application to US EPA, deviations from GLP can be noted and need not invalidate a study.

Implications, suggestions for change and benefits of change.

The primary concerns are:

1. Cost to obtain registration of agricultural and veterinary chemical products.
2. Time required to obtain registration of agricultural and veterinary chemical products.
3. Cost to maintain registration of agricultural and veterinary chemical products.

4. Differences/inconsistencies between controls on use, supply and storage of agricultural and veterinary chemical products in individual States/Territories.
5. Differences/inconsistencies between requirements for registration of agricultural chemical products in Australia and overseas trading partners.

The implications of a costly registration scheme are:

1. Reluctance of organisations to register their products for use in Australia. The impact of this includes:

    a) New technologies not being registered for use in Australia placing Australian primary producers at a disadvantage relative to their overseas competitors who have access to such new technology.
    b) Australian innovators not developing their products in Australia. Technology is transferred to countries in which it is easier to obtain registration or to larger markets where similar investment in registration will provide access to much larger markets.
    c) Products that should be registered being sold in Australia without registration potentially damaging the reputation of Australian commodities. This could adversely impact the acceptability of Australian commodities and produce in overseas markets, as well as potentially placing users, bystanders and the environment at risk due to the availability of products that have not been assessed for safety by a competent authority.

2. Without new technologies and new products being registered, Australian primary producers:

    a) Will need to continue relying on older technologies which may be more hazardous to people, the environment and trade than newer technologies that could be available if the registration system was more accommodating.
    b) May be excluded from certain markets that no longer accept commodities or produce that have been treated with certain products.
    c) May be prevented/inhibited from operating in certain areas, for example peri-urban areas. With increasing community concerns about environmental issues, there is increasing concern about the "footprint" left by transporting agricultural produce great distances. In other countries, for example the UK and USA, there is a movement to foster production of fruits and vegetables and other agricultural commodities close to urban areas. With continuing reliance on already registered agricultural and veterinary chemical products, many of which are viewed by the community as being "unacceptable" for use near their homes, the development of peri-urban agriculture is inhibited.
    d) Maybe prevented/inhibited from certain operations due to occupational health and safety, environmental and other considerations that might be adequately addressed by use of new products or through registration of new uses for existing products.

3. With inconsistencies in the control of use of agricultural and veterinary chemical products between different States/Territories, larger organisations that can provide economies of scale to production, including service organisations that provide advice to primary producers, will be placed at a competitive disadvantage to commonly less efficient local organisations due to the requirement of national organisations to develop nation-wide policies. In the case of service organisations supplying advice, including organisations that supply agricultural and veterinary chemical products to primary producers, the benefits of negotiating better pricing for the products they supply and access to a large pool of advice and information could result in primary producers paying higher prices for their agricultural and veterinary chemical products and not having access or having only limited access to the latest information. The problem of information supply is exacerbated by the reduced extension services available to primary producers from State and Territory agricultural advisers.

4. With inconsistencies in requirements between Australia and overseas countries, overseas suppliers of agricultural and veterinary chemical products are dissuaded from supplying their products into Australia and Australian innovators are discouraged from developing their innovations or are encouraged to develop and register their products outside Australia, resulting in Australian primary producers having delayed access, if any access at all, to such Australian innovations.

The Australasian Compliance Institute recommends that:

1. Permits issued for minor uses be automatically converted to registrations if no adverse effects are noted during the permit period. Such conversion should attract the minimum fee possible (currently $540) to encourage registrants of products to add those uses to their labels.
2. The fee payable for registration of new agricultural and veterinary chemical products be reduced to levels compatible with that payable for notification of the same chemical substance if it were to be considered an industrial chemical.
3. The fee payable to APVMA and the timeline for obtaining registration of products that can demonstrate a benefit to the community and/or the environment be reduced to encourage their development and registration. In many situations, the main beneficiary of new technologies is the environment or the community as a whole. The cost of bringing these benefits to Australia should be shared by the community through significant contribution of public funding to the operation of APVMA. This might be achieved through subsidies for registration of products that can show a demonstrable benefit relative to older, currently available technologies.
4. Applicants for approval and/or registration of substances be permitted to submit assessment reports from overseas regulatory authorities to enable further reductions in the fees payable to APVMA for registration of new active constituents or new agricultural and veterinary chemical products.
5. The time required for approval and registration of agricultural and veterinary chemical products be reduced by:

a) Eliminating the need for chemical substances that are only used in the workplace (e.g. commercial agricultural production) to be Scheduled as Scheduling imposes a significant delay in the approval process for new active constituents. Scheduling is not required for other chemical substances used in the workplace only. Scheduling can remain a requirement for veterinary chemicals and agricultural chemicals sold to consumers.
b) Accepting and relying on evaluations conducted by other regulatory authorities with effective regulatory systems. Such reliance would then allow the APVMA to concentrate on Australia specific issues.
c) Outsourcing evaluations where internal resources are inadequate in the same way that other authorities (for example, the EU and USA) use external resources for initial evaluations.
d) Streamlining the process for registration by increased grouping of products. This is likely to require registration applicants to develop and justify their own criteria for grouping target crops/animals and the effects that products have, for example, products that are known to control a particular pest species might be able to be registered for use on any crop due to the similarity of the behaviour of the pest on all crops and the susceptibility of the pest to application. In other situations, it may be necessary to demonstrate efficacy on individual situations/crops/animals.
e) Reducing the cost of developing residue data by allowing studies to deviate from strict GLP provided the deviations are explained.

6. Reviewing State and Territory legislation that impacts use, storage and transport of agricultural and veterinary chemical products and develop a single, unified system to overcome the inconsistencies between States/Territories and between the State/Territory legislation and Federal requirements. Commonwealth regulation may be required to ensure cross-jurisdictional uniformity in the use of registered agricultural and veterinary chemical products.
7. Providing data protection for information supplied in support of applications for permits in the same way that data submitted in support of registration for registration are protected.
8. The effectiveness of the registration system be enhanced by establishment and maintenance of an enforcement system that ensures unregistered products are quickly removed from the market and compliance with required industry codes of conduct are supported by effective regulatory action by the National regulator (APVMA). This requires greater flexibility in the enforcement options available to APVMA than only prosecution under the Criminal Code, in the same way other regulators have brought "tools" available to ensure compliance.
9. Establishing an independent audit or review panel to review APVMA decisions as small business is deterred from challenging decisions by the cost of the existing legal process.