

39 O'Connell Street  
North Melbourne  
Victoria 3051  
p: +61+(0)3 9329 3511  
f: +61+(0)3 93293522  
e: [applenpear@apal.org.au](mailto:applenpear@apal.org.au)



**Apple & Pear Australia**

PSIC Secretariat  
Agricultural Productivity Division  
Department of Agriculture, Fisheries and Forestry  
GPO Box 858  
CANBERRA  
ACT 2601

13 April 2011

Dear Sir

**Re: Consultation Regulation Impact Statement: A National Scheme for Assessment,  
Registration and Control of Use of Agricultural and Veterinary Chemicals.**

Thank you for the opportunity to comment upon the Product Safety and Integrity Committee's consultation paper regarding reforms to the regulation of agricultural chemicals.

Apple & Pear Australia Limited (APAL) is the peak industry body representing the interests of commercial apple and pear growers in Australia in matters of national importance including regulation and legislation, marketing, research and development.

APAL is fully supportive of measures to improve the efficiency and effectiveness of agricultural chemical regulation. It is important that reforms are made to cut unnecessary red tape and to provide farmers with access to cheaper, modern, cleaner and safer chemicals. Chemicals are an essential tool in underpinning the productivity of Australian orchards, and it is important to ensure that there is a suite of chemicals available for different purposes to avoid chemical resistance in pests and diseases and against weeds.

As an initial comment, I would point out that the time allowed for consultation is far too short given the complexity and importance of the issues. It would also appear that chemical users will not have an opportunity to comment upon the preferred reform options before they are put to the Primary Industry Ministerial Council or the Council of Australian Governments. But further extensive consultation is required because the Product Safety and Integrity Committee has failed to fully document how each of the options might operate in practice and how they might be implemented. The Committee has also failed to provide any level of detail on the relative costs of each option, making it difficult for industry to rank alternatives. Further, with no mention or discussion made

with respect to funding mechanisms, chemical users are left to assume that a full cost recovery system will be adopted even though many of the inefficiencies in the current regulatory framework exist because of inherent market failures.

In response to your consultation paper, APAL raises a number of specific issues of concern, as detailed in the Attachment.

I ask that you reconsider the process and timelines for delivering a detailed regulatory model for a single national framework for agricultural chemicals so that industry and chemical users can provide appropriate input into these significant reforms.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Jon Durham', with a long horizontal flourish extending to the right.

Jon Durham  
Managing Director

## **ATTACHMENT A:**

### **APAL Response to Consultation Regulation Impact Statement**

#### ***1. Assessment and Registration***

APAL supports the development of a transparent overarching risk framework for agvet chemicals to manage a range of potential risks from chemicals, including issues such as public health, occupational health, residues and trade, and risks to the environment. However it is important that this framework is underpinned by sound science and that decision making takes an evidence-based approach.

APAL is also generally supportive of the broad recommendations to improve efficiencies in the assessment and registration process. This includes limiting application screening to an administrative completeness check, providing an upfront pre-registration assistance session to applicants, preventing the applicant from changing categories after lodging an application, restructuring assessment timeframes to take greater account of

elapsed time, time limits for an applicant to submit data to the APVMA, extensions to timeframes based on mutual agreement and providing an optional accelerated assessment process. Moves to improve the efficiency of registration should reduce the costs faced by chemical companies and encourage them to seek the registration of new chemicals or broader uses on label for chemicals into the Australian market.

There are however, several areas in which APAL does have reservations. These relate to a) proposals to limit requirements for efficacy and trade data in the assessment process; b) chemical reviews, and c) the use of the precautionary principle. These concerns are detailed below:

**a) *Efficacy and Trade Data Requirements***

Trade and efficacy assessments of chemicals play an important part in the value chain of apples and pears. Assessments for trade risk provide the necessary safeguard for ensuring that the apple and pear industry can gain and maintain access to export markets. Ensuring that Australian products remain safe for consumers provides an important intangible that underpins the Australian brand.

As noted by the Product Safety Integrity Committee (the Committee), market incentives to avoid jeopardizing trade and market access exist only up to a point. APAL supports the view that the impact of a trade incident could have implications beyond those borne by a single grower, beyond those borne by one agricultural industry and beyond those borne by one chemical company. For this reason, APAL supports the Committee's proposal not to exclude trade data requirements in the assessment process of most chemicals. APAL supports the recommendation that trade data should only be excluded for products designed to be used outside trade related industries.

APAL also believes that efficacy assessments are important as they confirm whether a product performs as claimed. For major use chemicals it is also important that efficacy data is relevant to Australian conditions and production systems. Removing the efficacy requirement from the registration assessment process could potentially encourage chemical companies to dilute their label claims in order to speed up the registration process.

We also note that under Australian consumer law manufacturers would bear ultimate responsibility for proving product effectiveness. However challenges to a product's effectiveness would generally only come "after the fact" when crops have failed or have been adversely affected by the application of a chemical. Such challenges are likely to be costly because a multiple of variables impact upon an orchard at any one time and disentangling the impact of a chemical could prove both complex and costly. APAL therefore supports the retention of the APVMA requirement that efficacy data be provided as part of the registration assessment process. For high risk chemicals this requirement essentially acts as a form of agvet chemical user protection.

However there may be a case for reducing efficacy requirements for very low-risk products, including those of biological origin and pest control devices such as insect traps, to ensure that assessment standards are proportionate to the risks involved.

Additionally, APAL believes that efficacy data may be unnecessary in permit application processes. Permit applicants tend to be chemical users or their representatives and it is unlikely they would seek a permit for a product that didn't work or meet their commercial needs. Instead, efficacy data requirements constrain access to, and hence impede productivity improvements from, chemicals for use in minor crops, for use against minor pests in major crops or for use on individual varieties that do not appear on labels.

APAL also supports the Committee's proposal to develop a common approach to product efficacy across jurisdictions to limit label complexity. We agree with the view that more effective communication through labels could lead to substantial benefits from users having a clearer understanding of how to apply, and how not to apply, agricultural chemical products. The apple and pear industry also supports the proposal to require chemical companies to place all their market labels on a single web based database. A single repository which provides a comprehensive and comparative listing of product label details will enhance information flows, improve user knowledge and skill and boost competition in chemical supply.

#### *b) Chemical Reviews*

The Product Safety and Integrity Committee suggests that to manage aggregate risk, agvet chemicals should continue to be registered only if they are assessed as meeting **contemporary** health and safety standards. The Committee also notes that the APVMA's existing chemical review program does not allow it to focus on this level of rigour on all chemicals. In response, a number of options are proposed, including:

- Develop a targeted re-application program - this would expand the ongoing risk prioritised reviews currently carried out by the APVMA;
- Require re-registration of all active constituents.

APAL does not see the need for the review of all agvet chemicals or active constituents as this places the onus on chemical companies to prove at regular intervals that their products remain safe. Instead the current practice of reviewing registrations when **new research or evidence** has raised concerns about the use or safety of a particular chemical or product should be retained.

Generic chemicals, those which are off patent and those about to lose data protection are of particular concern to Australian apple and pear growers. APAL believes that it may not be profitable for chemical companies to update the data and information

required to support the continued registration for such chemicals and as a consequence will be withdrawn from the market. This in turn would result in a reduction in pest management options and adversely impact on the competitiveness of Australian apples and pears.

Whilst APAL acknowledges that it is important that chemicals meet 'contemporary standards', such standards need to be based on sound science and established within a risk rather than hazards based framework. APAL supports a targeted re-application, review and re-registration system where reviews are undertaken in light of new scientific information or concerns. The adoption of automatic periodical checks and sunset clauses is likely to add to uncertainty and raise costs (which will ultimately be passed onto growers) and reduce the availability of chemicals to Australian growers.

Where chemical reviews are undertaken, APAL also supports measures that will ensure more timely completion to remove uncertainty in grower's future access to these chemicals.

### **c) *Precautionary Principle***

The Product Safety and Integrity Committee presents two options with regard to the precautionary principle:

- Adopt the precautionary principle in all instances where the science is uncertain;
- Take an explicitly precautionary approach to human health and maintain the current risk based approach on all other matters.

APAL is concerned that the precautionary principle is ambiguous and is interpreted in different ways by different organizations and people. Without a clear definition it will be very hard to establish what the costs or benefits might be of applying the precautionary principle to the assessment and review processes of product registration and permits.

APAL does not support the elevation of the precautionary principle on all matters where the science is uncertain. Even with a clear definition, it is likely that the application of such a principle would impede access to agvet chemicals, with consequential adverse impacts upon the productivity of the Australian apple and pear industry.

## **2. *Access of chemicals in the apple and pear industry***

Agricultural chemicals used in apple and pear orchards are accessed in three ways:

- On label, according to the registered specifications established on that label;

- Off label with a minor use permit issued by the APVMA or a state regulatory authority;
- Off label without a permit and subject to the restrictions established by the regulatory authority in those states which allow such use.

It is our belief that a significant proportion of all chemicals applied within the apple and pear industry are on-label.

Off label use via minor use permits are uncommon, although not unheard of, in this industry. This is because most applicable pesticides are registered for pome fruit as they constitute a 'major crop' (based on area under orchard / domestic production and consumption levels). Additionally, most pest and diseases of apples are "major" in that they are endemic to most apple and pear regions.

Nevertheless, the ability of apple and pear growers to access minor use permits remains important. For example, the APVMA has issued a permit for the use of Delan 700 WG Fungicide in NSW and Queensland for the control of Alternaria leaf blotch and Alternaria fruit spot in gala, Pink Lady™ and red delicious apples. As a registered chemical, this product can only be used for the control of Black spot/apple scab and Bitter rot (*Glomerella cingulata*). However, as the NSW Department of Primary Industry<sup>1</sup> suggests, a conscientious move by growers to only apply this fungicide in response to weather conducive to black spot development may have led to the emergence of diseases such as Alternaria which had not previously been a problem. Alternaria is a devastating disease which infects high-value varieties. Apple trees can lose all of their leaves within a few days, which weakens the tree, exposes fruit to sunburn, and reduces the reserves produced by photosynthesis (leading to reduced fruit quality next season).

If the permit system of access did not exist apple growers would have been forced to incur the significant costs involved in generating the scientific data necessary to support registration of the chemical for the control of use of Alternaria. Although apples are a major crop it is unlikely that the chemical company would have been prepared to invest in the required data generation to support for the use of the chemical against Alternaria in a market as small as Australia.

Although the apple industry does not generally face a shortage of approved crop protection products, there is a potential for such shortages to arise as products are reviewed by the APVMA. This is a very real possibility if either Dimethoate or Fenthion were to be removed from the market in the near future. The permit system provides a good back-up against such scenarios by providing greater flexibility in the access of labelled chemicals. Additionally, pest resistance to existing chemical solutions is an ever present threat in agriculture and growers must have ready and easy access to chemical

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<sup>1</sup> <http://www.dpi.nsw.gov.au/archive/agriculture-today-stories/october-2007/help-for-apple-industry>

alternatives should the situation arise. The permit system provides such access to industry so that growers can remove resistant pests and diseases avoiding the long delays that would occur if registration (and the supporting data requirement processes) were required.

The ability to access chemicals off label is also important to those parts of the apple industry which require growth regulators. For example, the chemical Cytolin is commonly used in the apple industry to improve fruit shape (or typiness - the ratio of length to diameter - in certain varieties) and achieve increased fruit size. However, Cytolin is also occasionally used to assist with flower thinning and to stimulate lateral branch growth. Growth regulators are important to the industry. The use of flower thinning chemicals such as Cytolin reduces the need for hand thinning which is expensive in a high labour cost country such as Australia. As a lateral growth stimulant, Cytolin is also important for encouraging the right type of growth in young stock, particularly in high density systems.

The registered label for Cytolin indicates that it can be used for flower thinning for Red Delicious and Gala apples (if followed by treatment with a specific organic plant hormone<sup>2</sup>). But the importance of varieties change over time and using Cytolin as a flower thinning agent for other varieties, such as Cripps Pink, Fuji or Jazz is not permissible as an on-label use. Similarly, Cytolin can only be used to stimulate lateral growth for Red Delicious apples and not other varieties. However there is widespread anecdotal evidence to suggest that Cytolin is efficacious in providing the same outcomes in other varieties that can be achieved in Red Delicious variety.

Lime sulphur is another good example. The product is labelled for use in apples for the control of Black Spot and powdery mildew. It is not labelled as a chemical thinner. Nevertheless, growers in some states have found that it is particularly useful to thin 'hard to thin' varieties such as Gala and Fuji.

As indicated above, apple and pear growers currently access chemicals through all three existing means (label, off-label on permit and off-label off permit), depending upon jurisdiction. It is important, therefore, that undue hardship is not faced by growers as a result of any change brought about by harmonisation. That is, if access is currently available to growers, such access needs to continue. If that requires data generation to support that use being brought onto a label or onto a permit, then the costs of undertaking that exercise must be borne by government. Furthermore, if the existing APVMA definition of permit uses would not allow that use to be incorporated onto a permit then the definition must be widened to incorporate anomalies that might exist.

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<sup>2</sup> Naphthaleneacetic acid (NAA): an organic compound which is a plant hormone and is an ingredient in many commercial plant rooting horticultural products; it is a rooting agent and used for the vegetative propagation of plants from stem and leaf cutting. It is also used for plant tissue culture.

### **3. *Issues of Concern to Apple and Pear Growers***

Ready access to low priced, modern, clean, safe and efficacious chemicals is of key concern to the Australian apple and pear industry. Growers note that a number of developments and interactive forces are stifling access and use, including:

- The on-going availability of alternative classes of product is crucial to the management of the integrity of any one chemical product. Continued use of one product can lead to pest and disease resistance. It is APAL's understanding that this has become a major issue overseas. Additionally, the increasing use of soft chemicals in response to environmental concerns and a move away from broad spectrum chemicals can mean that minor pests can become major ones.
  - Governments and regulatory authorities need to develop incentives to encourage chemical companies to invest in the development of new products and make them available to Australian farmers.
- Extraordinary use patterns creating supply shortfalls. For example, the recent wet weather across many parts of the country has resulted in a significant increase in the demand for some agricultural chemicals. This problem can be exacerbated in cases where no viable alternatives exist on the Australian market.
  - Regulatory authorities need to be cognoscente of the implications of extreme weather patterns that may be associated with climate change
- Growers are legally required to apply chemicals in accordance with the label. However, in many instances growers would prefer to use the chemical at rates lower than those stipulated on the label. It is not in interest of the chemical companies to promote lower dosages but it is well known that the European experience has demonstrated that a large number of chemicals are efficacious when applied at lower than label rates.
  - Regulatory authorities need to review European studies and farm trials and incorporate those findings for the Australian chemical regulatory framework.

These issues are in addition to those already acknowledged within the Consultation Regulation Impact Statement and response to the earlier Discussion Paper "A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals" including, to name a few:

- Market failure and the associated disincentives for agricultural companies to place product into the small Australian market;
- The inefficiencies, costs and time lags associated with the Australian registration and permit processes;
- Inter-jurisdictional inconsistencies in control-of-use regimes;

#### **4. *Facilitating access to chemicals***

APAL agrees with the Committee that a number of initiatives would assist in getting a greater number of minor crops and/or minor uses onto product labels. These include:

- Development of assessment requirements that would utilise crop groupings and data extrapolation from existing registered uses. APAL would like to explore this option further, particularly because few details have been provided in regard to how such a list might be developed, whether it applies to major crops (to cover variety differences) or only minor crops, the conditions under which access might be granted and the costs of gaining registration or a permit, details of which have remain undisclosed.
- Generating a harmonized list of chemicals Generally Regarded As Safe (GRAS). APAL supports the use of GRAS as a means of providing access to users to non-toxic products and avoiding the costs of having such products entangled within the agvet regulatory system;
- Amending data protection legislation to provide protection for data used to register additional minor uses on existing products and to obtain permits. At present data protection only applies to the registration of new products but not to that generated for permit applications.
- Enhancing international collaboration including development of equivalent zones for acceptance of international efficacy and residues data.

Nevertheless, APAL supports the view that such initiatives alone are highly unlikely to overcome market failures where economic return does not justify the pursuit of registration or the generation of permits.

The Product Safety and Integrity Committee also propose a number of options to facilitate improved access to chemicals through the harmonisation of jurisdictional laws of what is permissible with regard to crops and or pests. The fragmentation of chemical access systems across the country can make it difficult to develop national programs, particularly those aimed at promoting product and process integrity in our international markets. Similarly, for those businesses that operate in a number of states it makes the QA and Food Safety programs more complex and costly. APAL believes that a single

national scheme for the control of use of chemicals would take away those inconsistencies and ultimately reduce input costs.

Although APAL agrees that a consistent national approach is both desirable and necessary, the options presented by the Committee contain a number of flaws. These are detailed below.

#### **4.1 Proposed Hierarchy System**

It is our understanding that the most liberal of the reform options includes a hierarchy whereby chemical users are directed to registered products, then permit products and finally to off label uses, according to a scale of availability and circumstances. In the first instance chemical users are directed to registered products and if the desired use appears on a label, the user must use that product (or choose between products if the desired use appears on more than one label).

Minor use permits are a primary back-up to that system. That is, only in circumstances where the desired use is not registered on a label can the chemical user scan products which have a permit. If the desired use appears on a permit the chemical user may access that product for that purpose.

Finally, the Committee proposes that if the desired use does not appear on either a label or on a permit, a grower may use a chemical product if it is approved for a similar use for another crop. Proposed caveats on the latter include: the crop for off label-off permit use is a minor crop; the chemical is neither an S7 nor restricted chemical, and the user is required to report the intended use prior to its farm application (to improve compliance and traceability).

APAL has a number of serious concerns with this proposal. First, the caveat that “off label - off permit” use be restricted to minor crops is too narrow. As indicated in Section 2 above, there are a number of instances where growers of major crops such as apples require access to chemicals that do not appear on label or on permit. A major crop does not, by definition, automatically mean that chemical companies have registered all appropriate uses. Although apples may indeed be a major crop in comparison to other Australian fruit crops, the Australian market for chemical use in apples is minute compared with similar markets overseas. Likewise, apple varieties differ in their relative importance in production systems across the globe and chemical companies generally focus only on those varieties which are important in major markets such as the US and Europe and not necessarily those produced in Australia. Additionally, just because pome fruit is defined as a major crop it does not follow that the Australian apple and pear industry can afford to incur the costs of producing data required by the permit approval process.

Second, there appears to be no incentive under this type of system for users to seek permits because minor users would simply rely upon the “last resort” of off label use. This has a number of implications:

- Maximum Residue Limits for that crop would not be established;
- Growers will not know what application rates are most efficacious for that use;
- Growers will not know who bears responsibility in the event of a failure or adverse experience - the user, the manufacturer or the source of advice.
- Trade could be jeopardised

#### **4.2 *More restrictive systems***

Some of these issues could be resolved if legal access to chemicals was confined to uses on labels and permits. However, as noted above, APAL could only support this option if there was a guaranteed mechanism and government funding for moving all current and all future minor and extraordinary uses onto permits in a speedy and low cost way. The Committee has already noted that growers in a number of jurisdictions would be significantly adversely affected by a move to prevent off-label off permit uses. This would include the many apple growers in some jurisdictions who use chemicals such as Cytolin and lime sulphur as explained above. The Committee ought to consider ways in which the government could fund the transfer of these types of existing (and future) uses onto permits, removing the adverse impact on growers within the more liberal jurisdictions and extending the use of those chemicals to growers in other jurisdictions. A suitable transition period to enable growers to adjust would be required.

Going forward, the Committee ought to consider ways how government might fund and prioritise the incorporation of new chemicals, new uses and new technology into the permit system (in the event that market failure prevents their registration). Some assurance that a government funded permit system does not discourage chemical companies from seeking full registration and approved labels would be required. For example, data protection should be extended to the chemical manufacturers who offer data to develop permits, with a framework in place for this permit to potentially progress to a labelled use.

#### **5. *Residue Testing***

The apple and pear industry has been very proactive in establishing its own national residue testing scheme on the philosophy that all agricultural industries should be able to demonstrate compliance with Australian food standards. Monitoring such as this has fundamental benefits for future market access and consumer confidence, both domestically and internationally, as demonstrated in the requirements of some South East Asian markets.

APAL therefore supports – ‘in principle’ - the establishment of a national program for monitoring residues and contaminants in agricultural commodities. The Product Safety Integrity Committee has failed, however, to detail how a national scheme might operate alongside existing schemes. For example, the Committee has not specified whether a national scheme would replace or dovetail with the apple and pear industry national residue testing scheme. Serviced by the National Residue Service of DAFF, the Apple and Pear Monitoring Scheme has operated successfully for many years. With fruit taken from both orchards and the wholesale markets, the scheme tests a random selection of the commodity for both residues and contaminants but does not test the environment. This is appropriate given that the scheme is funded by a grower levy. Testing the environment would introduce an element of public good and that component should be funded by other means.

APAL would be very concerned if the Apple and Pear Monitoring Scheme were to be replaced by a generic monitoring scheme. The residues and contaminants included within the Apple and Pear Monitoring Scheme are specific to the pome fruit industry. It therefore provides confidence to both the industry and consumers that best agricultural practices with regard to chemical use are employed. A generic list of chemicals and contaminants would lessen the degree of confidence, which may ultimately create a demand for additional and costly testing schemes. Consideration should be given to providing a ‘base’ chemical list for all commodities with the ability to ‘top-up’ for specific industries.

Prior to submitting a detailed proposal to COAG, the Product Safety Integrity Committee should provide industry with a specific framework as to how a national monitoring and surveillance scheme might operate. This would include details in regard to the breadth of chemicals to be tested, how the system fits with the National Residue Service and other programs such as Freshtest, and the precise manner in which the national scheme would be funded. More detailed information would enable constructive consultation between the parties.

## **6. *Record Keeping***

APAL supports the establishment of a national requirement that agricultural chemicals users maintain auditable records of use. A significant proportion of apple and pear growers already keep records, as this is a condition of their participation in Quality Assurance Schemes as required by their buyers, most particularly the major retailers.

However APAL notes that record keeping requirements must be kept to a minimum. They should be sufficient only to meet the objectives of controlling use to support risk management and provide trace-back. Record keeping must not be onerous – introducing time consuming and complex record obligations would simply increase costs (borne by growers) and discourage participation.

## **7. Chemical Use Training**

APAL believes that training and accreditation in chemical use is an important element of risk management: to ensure the integrity of the fruit produced and the safety of consumers, the safety of farm employees and appropriate duty of care for the farm environment. APAL therefore supports – ‘in principle’ - the establishment of national competency requirements for chemical users where those requirements are based on risk and are consistent with the levels of risk assumed in the assessment and registration process.

APAL supports the view that a nationally-consistent training and competency regime would contribute to consistent risk-management outcomes and lead to cost-savings for chemical users operating in multiple jurisdictions. Most importantly it would provide a known floor to the chemical use competence of apple and pear producers which in turn supports the integrity of the product from a customer viewpoint. Additionally it could overcome the problem that inconsistent state and territory regulations might have on the implementation of industry initiatives (such as integrated pest management).

However considerable consultation is required before the base level of competency is established. APAL understands that in registering products and approving label directions, the APVMA currently assumes that all chemical users have the skill to follow those directions – that is, they have at minimum, AQF level 3 qualifications. Details of the cost of meeting such requirements, the training hours involved, the manner in which training could be delivered and competency demonstrated, and the way in which training should be funded should all be specified more clearly by the Product Safety and Integrity Committee.

Similarly the Committee should assess the gap between their preferred base level of competency and those competency levels required under existing Quality Assurance Schemes. As with record-keeping, a significant proportion of apple and pear growers already undergo training for on-farm chemical use as part of the Quality Assurance Schemes required by their buyers. It is important that any competency requirements do not add to the regulatory burden faced by those farm enterprises which are compliant in chemical use competency. Other avenues should be sought to change the behavior of the small proportion of non-compliant users.

## **8. Licensing**

APAL does not believe that agricultural enterprises should be licensed for the purposes of regulating access to chemicals and providing a trace-back mechanism for chemical use. The Committee has proposed an option that suggests agricultural enterprises, with more than one chemical user (say, the proprietor and a farm labourer), should be treated the same as commercial fee-for-service chemical providers such as crop sprayers, aerial sprayers, and chemical resellers.

If the control of use regulations were designed such that all chemical users are required to undertake basic training and keep records of chemical use then licensing of agricultural enterprises would not provide any additional benefit. Instead licensing would simply add an additional layer of regulatory burden that growers could ill afford.

## **9. Funding**

As noted by the Productivity Commission (2008, p226) control-of-use regulation of agvet chemicals is currently funded by states and territories largely from consolidated revenue at a cost of around \$10 million per annum. The Productivity Commission also argued that expenditure on a national regime “may need to increase if an evaluation of the existing arrangements for monitoring and compliance enforcement finds them to be insufficient for appropriate management of the risks”. APAL is disappointed that the Product Safety and Integrity Committee has failed to quantify the size of the increase in expenditure required by harmonisation. The failure to document the funding alternatives associated with the reform proposals and the implications for chemical users is also of considerable concern.

Additionally, APAL believes that it is important that the Government fund any data generation required to operate a nationally harmonized system that prohibits off label - off permit use. APAL understands that in order to achieve harmonization across jurisdictions, the government may require that current “less-regulated uses” (such as in Victoria) – and any future use – are brought onto the permit system. As this represents a change in policy government has an obligation to fund it.

More importantly, government should recognize that the permit system itself exists as a means of overcoming market failure. That is, the off label use of a chemical arises because economic returns are deemed insufficient to warrant the manufacturer investing in the registration process to cover all possible uses for the product. But the market failure extends to chemical users as well. In this case there is a free-rider problem: no one user would incur the cost of undertaking the data generation required of a permit application because no other users could be excluded from accessing that product.

The existence of the market failure issue has been well recognized internationally. Governments in the US and Canada, for example, have responded by establishing systems to extend chemical access by operating budget funded minor use permit schemes. The Product Safety and Integrity Committee should recommend that a scheme such as the US IR-4 program and the Canadian Minor Use Pesticides Program be adopted in Australia. As part of a new round of consultations with stakeholders, and before any detailed policy proposal is put to COAG, the Committee should provide specific information as to how such a system might operate in Australia and how it

would improve grower access to new and effective chemical tools for use in minor crops and for minor (or extraordinary) uses in major crops.

It is important that such schemes are largely funded by consolidated revenue and not by industry. Overcoming the cost issue associated with market failures is only one rationale. Improved chemical use (through more rigorous assessments to achieve permit status) provides a positive flow-on effect to the wider environment and on food security. These flow-on effects would not be captured by farmers if they were to bear the costs of generating data required of a permit application. Additionally, the cyclical and variable nature of agricultural incomes impacts upon the capacity of chemical users to pay and this in turn can compromise the regulatory system.

## **10. Governance**

APAL believes that the issue of the governance of chemical registration, control of use and other regulatory functions (training, licensing and accreditation) is subordinate to decisions regarding how a national single framework for chemical access might operate. The options to create two organisations, of amalgamating state functions into the APVMA or to have service agreements between the Commonwealth and the states must be fully costed to determine which will deliver the COAG objectives at least cost.