Representing the Plant Science Industry

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26 November 2013

Mr Tony Shepherd AO
Chair
National Commission of Audit
Email: submissions@ncoa.gov.au

Dear Mr Shepherd

Re: Submission to National Commission of Audit

CropLife Australia (CropLife) is the peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of chemical crop protection products and agricultural biotechnologies. The plant science industry provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies that are key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $1.5 billion a year to the Australian economy and directly employs thousands of people across the country.

CropLife and its members are committed to the stewardship of their products throughout their lifecycle and to ensuring that human health, environment and trade issues associated with agricultural chemical use in Australia are responsibly and sustainably managed. Our member companies spend more than $13 million a year on stewardship activities to ensure the safe and effective use of their products. CropLife ensures the responsible use of these products through its mandatory industry code of conduct and has set a benchmark for industry stewardship through programs such as ***drum****MUSTER*, ChemClear® and Agsafe Accreditation and Training. Our stewardship activities demonstrate our commitment to managing the impacts associated with container waste and unwanted chemicals.

CropLife appreciates the opportunity to provide input to the Commission of Audit ('the Commission') and would like to draw your attention to the following areas of government that we consider could be made more efficient and effective through the Commission's activities. I provide this letter as a brief overview of such issues but am happy to provide a copy of a large number of detailed and comprehensive submissions on these issues that CropLife has submitted over the last few years to other relevant inquiries in respect of these issues.

1. Agricultural Chemical Regulation

Agricultural chemicals are impacted by a swathe of regulation at all levels of government. Regulation has a significant impact at every stage of the life cycle of a chemical product. Manufacture, storage, transport, sale, use and disposal are all heavily regulated. Despite significant efforts by industry over several years and purported commitments by successive governments, the total burden of regulation remains high and continues to increase.

Reform is necessary because the current system is seriously inefficient. It is important to note that while increased efficiency is required all independent reviews of the system have shown that there is no failure in its efficacy. Regulation of agricultural chemicals is currently an inefficient and time intensive process that needs improvement. CropLife is concerned that the newly amended *Agricultural and Veterinary Chemicals Legislation Amendment Act* (Cth) that will come into effect on 1 July 2014 will, in fact, only increase inefficiency and cost. This will result in Australia's farmers paying more for critical crop protection products, reducing access to existing agricultural chemistry tools and discouraging new, innovative crop protection products being bought to the Australian market.

The Act in its amended form:

- Introduced mandatory re-registration of agricultural and veterinary chemicals every 7-15 years. This clearly duplicated the Chemical Review Program [1] undertaken by the Australian Pesticides and Veterinary Medicines Authority (APVMA), which was already in place and provided the opportunity to review chemicals that posed any concerns. CropLife supports the regular review of chemicals to ensure their safety and efficacy.
- Increases costs for registrants and applicants. The APVMA's Cost Recovery Discussion Paper suggests that registrants and applicants will be charged an extra $8 million (around 30%) each year.
- Precedes key COAG control of use reforms that will have an impact on APVMA risk assessment presumptions.
- Removes flexibility for applicants and the regulator:
    - Provisions to shut the gate for new data may be too inflexible and limit the capacity for applicants to rectify applications where new data requirements are identified by the regulator. This may result in **more** application refusals, subsequent applications and cost;
    - Provisions preventing applicants to change application categories after submission will lead to more application refusals and subsequent applications with additional cost; and
    - Fixed time periods may not reflect the wide range of potential applications and associated regulatory requirements.
- Will result in loss of existing products and discourage and delay introduction of new products:
    - Greater regulatory costs will remove products that have small markets – such as for minor uses or specialty crops;
    - Continuation application process may cancel useful products that are safe and effective to use; and
    - Excessive and unnecessary regulatory burden reduces incentive for innovation by industry, with negative consequences for investment in new products.
- Does not increase efficiency or reduce red tape:
    - New pre-application assistance provisions increase the functions of the APVMA without increasing its resources;

[1] http://www.apvma.gov.au/products/review/

- Reduced flexibility is likely to increase the number of applications refused and lead to subsequent applications at additional cost, decreasing APVMA efficiency; and
- New measures for continuation applications duplicate existing APVMA powers.

- Ignores significant potential areas of reform including:
  - Changes to APVMA product scope to focus on core business;
  - Changes to risk assessment scope to reflect changing regulatory environment; and
  - Fails to remove obsolete administrative structures (such as the Advisory Board).

CropLife is confident that the Coalition's election policy commitment to repealing the previous government's recently passed legislation imposing re-registration requirements will increase the efficiency of the Australian Pesticide and Veterinary Medicines Authority. This should be a matter of priority to minimise

CropLife's previous submissions to Government on this issue can be found at:

- http://www.croplifeaustralia.org.au/submission/senate-committee-rural-regional-affairs-transport-respect-agricultural-veterinary-chemicals-legislation-amendment/
- http://www.croplifeaustralia.org.au/submission/second-exposure-draft-of-the-agricultural-chemicals-legislation-amendment-bill-2012/

2. Minor use

CropLife has long advocated for the introduction of a comprehensive, publicly funded program for minor uses of agricultural chemical products.

An appropriately targeted, moderately funded minor use program in Australia can safeguard Australian agriculture by increasing its productivity and diversity. Countries such as the United States have had a minor use program for decades. Economic analysis of the United States' minor use program has estimated that for **every dollar invested, the program facilitates a return to the United States' economy of US$500**.

The Coalition's pre-election commitment to allocating $8 million to a minor use and specialty crops program is significant. The previous government failed to implement or fund a minor use program. It instead implemented a National Produce Monitoring Scheme within the Department of Agriculture at a cost of $25 million over 5 years. The scheme's sole function is to identify known issues that a minor use and specialty crops program would solve, thereby making a minor use and specialty crops program a significantly better investment for the $25 million. Most estimates suggest that a targeted, moderately funded minor use program in Australia would require one off funding in the order of $45 million.

CropLife has previously submitted a proposal for an Australian minor use program to Government outlining a structure that could be adopted for this reform. The proposal has the support of the National Farmers' Federation and state based farmer organisations, together with producer groups such as AUSVEG, the peak industry body representing Australian vegetable and potato growers.

CropLife's previous submission to Government on this issue is provided at '*Attachment 1*'.

3. National Harmonisation of 'Control of Use'

CropLife promotes improved harmonisation of state control of use regulations in Australia to remove duplication and inconsistencies, and reduce unnecessary costs to industry. CropLife members find it difficult, confusing and costly to meet the multiple regulatory requirements of all the jurisdictions in Australia. Some state legislation in certain circumstances allows 'off-label' uses that are not risk assessed. Some off-label uses may therefore result in unacceptable risks to users, consumers or the environment. For these reasons, CropLife does not support off-label use of agricultural chemical products. A comprehensive, publicly funded program for minor uses of agricultural chemical products would enable registration of chemical products for use on minor and specialty crops, reducing the need for off-label uses and providing a platform for which national harmonisation could occur.

4. Nationally Harmonised Workplace Health & Safety Legislation

CropLife welcomes reforms to nationally harmonise workplace health and safety legislation. This process has the potential to significantly decrease current distinctions between jurisdictions that increase compliance costs for industry. However, we are very concerned that the elements of the reforms dealing with agricultural chemicals merely replace inconsistency between jurisdictions with inconsistency between regulators.

Our specific concern surrounds the removal of legislative recognition for labels approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA) as this legislative recognition is inconsistent with the existing APVMA risk based labelling system.

As a consequence and upon full compliance it will:

- diminish the current protections afforded to users, increasing health risks to workers;
- be inconsistent with existing labelling requirements administered by the APVMA; and
- be expensive, time consuming and impossible for registrants to comply with, and for governments to enforce.

This component of the new harmonised workplace safety laws will result in an increased risk to users of agricultural chemical products because of an inappropriate and duplicative chemical labelling requirement. CropLife sought to address this issue directly with Safe Work Australia without success. CropLife made many representations to Safe Work Australia on several occasions during the development of national harmonisation bill, however those concerns were not addressed prior to the bill's passage through parliament. Other industry groups expressed similar concerns, as did several Commonwealth, state and territory government agencies.

Agricultural chemical labels are the key communication system to provide users with critical information needed to enable safe use of that product. Labels operate within a comprehensive communication system for chemical safety. This includes Safety Data Sheets, training courses and stewardship schemes operated by industry. Inappropriate changes to labels will have impacts on the remaining communication mechanisms.

The Commonwealth Government Departments of Health, Agriculture and Environment all employ risk management principles when managing risks from agricultural chemicals. Internationally, the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) recognise that where risk-based systems are employed, some GHS elements may not be appropriate. CropLife International has worked with both the WHO and the FAO to outline how risk based systems should complement, rather than conflict with the GHS. This is reflected in the International Code of Conduct on the Distribution and Use of Pesticides that is itself adopted by the CropLife International and CropLife Australia Codes of Conduct. It is also reflected in the Guidelines for Good Labelling Practice for Pesticides being jointly developed by the FAO and WHO.

The problems with the Legislation and consequential regulatory problems can be simply remedied. We recommend reinstating the pre-existing recognition that labels approved by the APVMA are sufficient for workplace safety legislation. As these labels take into account workplace safety risks, they will not diminish the safety of workers that handle these products.

Without this recommended change, industry and government will be presented with an unworkable labelling system for agricultural chemicals that will be costly to implement, offer no improvement in safety and be impossible to comply with. This would be a bad outcome for all sectors of the Australian community.

5. Regulation of Genetically Modified Organisms (GMOs)

The plant science industry is subjected to significant duplication of regulation between the three main regulators of gene technology – the Office of the Gene Technology Regulator (OGTR), the APVMA and Food Standards Australia New Zealand (FSANZ). Unnecessary duplication of regulation is undesirable because it increases the regulatory burden for applicants with little or no associated benefit.

For example, in 1996 in the absence of other regulation a policy decision was made to treat biologically active GM genes/proteins as agricultural chemicals, even though they remained *in planta*. This policy decision allowed the APVMA to regulate genetically modified (GM) insect-resistant cotton prior to the establishment of the Gene Technology Regulator as the arbiter of dealings involving GMOs in Australia.

Currently, only the efficacy, residue and resistance management aspects of the APVMA's assessment of GM insect-resistant crops are not either duplicated by other regulatory agencies (such as the OGTR or FSANZ) or waived due to not being applicable to GM plants.

The APVMA system appears to recognise this duplication. The APVMA's *Guidelines for the Registration of Biological Agricultural Products* state that prior to the APVMA assessing a GMO, a 'record of approval' from the OGTR is required. In practice, this means that an OGTR risk assessment has already been conducted for every application to register a GM insect-resistant active ingredient or product through the APVMA. However, despite the apparent recognition of duplication, applicants are still required to submit a complete data package to the APVMA before a new insect-resistant GM crop can be brought to market. This duplication has significant cost and resource implications both for applicants and government.

Currently, the cost of the APVMA risk assessment is cost recovered from applicants, whereby the OGTR risk assessment is paid for through government appropriation funding. With the possibility of cost recovery for the OGTR currently under review by the Department of Health, there is the risk that if implemented, applicants could be 'double-charged' for what is effectively the same risk assessment. Like any regulatory cost in this sector this would eventually be passed onto growers and eventually consumers in the form of higher food prices.

A further major concern of the plant science industry is policy departments (for example the Department of the Environment) getting involved as quasi regulators in areas where they have no legislative mandate to do so. This is particularly the case in regard to the Department of the Environment's role in undertaking chemical and biological environmental risk assessments on behalf of the APVMA. By prescribing data requirements that go above and beyond those requested by the regulator, they are seeking to impose a significant, and unlegislated, additional burden on applicants in the sector.

A recent ABARES report[2] found that "Australia's regulatory environment governing the path to market of genetically modified food crops continues to impose an unnecessary burden on many agricultural businesses through inconsistent regulation and lengthy decision-making." The report concluded "the Australian Government could play a coordination role in negotiating for a shorter, well-defined regulatory path to market."

In conclusion, it is essential that the Australian Public Service's ability to provide high level, independent scientific and economic advice to the government of the day is strengthened through the activities of the Commission, within the context of eliminating wasteful spending and unnecessary duplication between regulatory agencies.

CropLife trusts that this submission will assist the Commission in identifying some of those areas of the scope, efficiency and functions of the Commonwealth Government in which we consider improvements can be made.

Please do not hesitate to contact CropLife's Policy Manager - Crop Biotechnology, [redacted] should you require any clarification in regard to any aspect of these comments.

Yours sincerely

[redacted]
Chief Executive Officer

[2] Gibbs C, Harris-Adams K and Davidson A (2013) *Review of Selected Regulatory Burdens on Agriculture and Forestry Businesses*, ABARES, Canberra.

CropLife AUSTRALIA

Representing Australia's plant science industry

ATTACHMENT 1

2013-14 PRE-BUDGET SUBMISSION

31 JANUARY 2013

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INTRODUCTION

CropLife Australia (CropLife) is the peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of crop protection and agricultural biotechnology products. The plant science industry provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies that are key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $1.5 billion a year to the Australian economy and directly employs thousands of people across the country.

CropLife and its members are committed to the stewardship of their products throughout their lifecycle and to ensuring that human health, environment and trade issues associated with agricultural chemical use in Australia are responsibly and sustainably managed. Our member companies spend more than $13 million a year on stewardship activities to ensure the safe and effective use of their products. CropLife ensures the responsible use of these products through its mandatory industry code of conduct and has set a benchmark for industry stewardship through programs such as ***drum****MUSTER*, ChemClear® and Agsafe Accreditation and Training. Our stewardship activities demonstrate our commitment to managing the impacts associated with container waste and unwanted chemicals.

The plant science industry's crop protection products include herbicides, insecticides and fungicides that are critical to maintaining and improving Australia's agricultural productivity to meet global food security challenges in coming decades. Each of these products is rigorously assessed by the Australian Pesticides and Veterinary Medicines Authority to ensure they present no unacceptable risk to users, consumers and the environment. Without access to these tools, farmers may potentially lose as much as 50 per cent of their annual production to pests, weeds and diseases. The productivity gains from the safe and responsible use of agricultural chemicals in minor crops and emerging industries are significant.

Crop protection products must be used sparingly, carefully and responsibly. The responsible use of agricultural chemicals must be supported by a regulatory scheme that maximises the benefits associated with their responsible use, while minimising the costs from excessive, inappropriate and ineffective regulation. Farmers need these products because of the benefits they provide to their businesses. While it is important for governments to provide for appropriate and rigorous regulation of pesticides and biotechnologies, any regulation must be mindful of the effects that poorly considered and excessive regulation will have through increasing production costs, discouraging investment and innovation, while not delivering any improvement in safety, health or environmental outcomes.

The 2013-14 financial year represents a period of significant change for registrants and developers of agricultural chemical products. New approaches to regulation potentially involve significant additional cost to registrants that may have detrimental impacts on the capacity of companies to provide Australian farmers with innovative new products. The Australian Pesticides and Veterinary Medicines Authority's (APVMA) Cost Recovery Discussion Paper highlights the significance of some of these costs[3] associated with unnecessary regulation. However, the focus on ensuring that Australia's regulatory system for agricultural chemicals is effective and efficient provides an opportunity for governments to ensure that it has all the necessary tools in place to support Australian innovation in agricultural production.

[3] http://www.apvma.gov.au/consultation/public/2012/interim_cost_recovery.php

This submission identifies those areas where additional investment by governments is required to continue to drive innovation and to ensure that Australia's regulatory system for agricultural chemicals can rapidly respond to emerging issues and facilitate Australian farmers' ability to compete in global markets.

For noting, the plant science industry has also been providing Australian agriculture with the benefits of crop biotechnology in the form of genetically modified (GM) crops since 1996. The utilisation of these innovations has delivered significant benefits in producing safe and affordable food, feed and/or fibre to the nation and the world. GM crops that are in the innovation pipeline have the opportunity to further improve the environmental benefits by allowing more efficient use of water, nutrients and other crop production inputs. Future GM crops will produce healthier oils and starches and other major human health benefits, as well as have a greater tolerance of salinity and acid soils.

Similar to the regulatory approval process for crop protection products, every GM crop in Australia is subjected to intense scrutiny and rigorous regulatory assessment. The Gene Technology Regulator approves all aspects of research and development with genetically modified organisms (GMOs) and any new GM crop product. Food Standards Australia New Zealand is required to approve any GM food ingredient and the APVMA regulates those GM crops with in-built pest protection. The GM canola and GM cotton crops that are grown in Australia have passed all of these regulatory assessments and delivered Australian farmers $407.7million[4] in additional farm income benefits during the period 1996-2010.

Emerging global food security challenges highlight the critical need to properly support Australia's farming sector and the critical supporting industries to agriculture, such as plant science. Should the following identified activities and initiatives be funded and implemented, they would complement current reform processes and result in a comprehensive package of reforms.

Australian agriculture and its associated industries generate over $150 billion each year and underpin 12.1 per cent of Australia's GDP. The agricultural chemical and biotechnology industry is an integral input driving this performance.

[4] Brookes G and Barfoot P (2012) 'GM crops: global socio-economic and environmental impacts 1996 – 2010', PG Economics, Dorchester, United Kingdom

PROPOSED REFORMS

1. Introduction of a comprehensive, publicly funded program for minor uses of agricultural chemical products

Attachment A outlines one proposed structure that could be adopted for this reform. Currently, agricultural chemical products are only registered in circumstances where there is an economic incentive to do so. Registrants will only register a product provided the cost of doing so can be recovered through sales. As the cost of developing data and registering products continues to increase, the risk that growers of minor crops will not have adequate tools to control pests, weeds and diseases increases. The small size of Australia's crop protection product market on a global comparison means that it is critical for the Government to implement this initiative so that Australian agriculture is assured access to the latest innovations from the plant science industry despite the cost inhibitors connected with the APVMA registration system.

A lack of pest and weed control options has a number of consequences. Farmers may be forced to rely on a permit system that is not ideally suited to facilitating the development of new uses on product labels. Should a farmer not have access to a registered or permitted product, they may be forced to rely on some state legislation that may in some circumstances allow 'off-label' uses. Off-label uses are not risk assessed. Some off-label uses may therefore result in unacceptable risks to users, consumers or the environment. For these reasons, CropLife does not support off-label use of agricultural chemical products.

A lack of available pest and weed protection products provides a significant barrier to the development of new agricultural industries. New crops are less likely to be commercially cultivated for domestic and export markets if there are no options for pest control. Horticultural crops in particular face challenges as the smaller areas under production often make it uneconomic for registration of new chemical products.

The consequences are not limited to minor crops. Major commodities such as wheat and barley can still be susceptible to minor pests and diseases that are not significant enough to justify investment by registrants to extend labels or develop new control technologies. Pests may not always be a problem for a particular crop, or unusual and unexpected weather conditions in a particular season may lead to new pest and disease pressures.

Australia's smaller market size (when compared to the United States, Europe or Canada) means it is uniquely susceptible to the effects of excessive regulatory cost on the availability of chemical products for minor uses.

Other countries such as the United States have had a minor use program for decades. As a result of the targeted investments made by that program, the United States' production of horticultural products as a proportion of agricultural production is significantly greater than in Australia. Economic analysis of the United States' minor use program has estimated that for **every dollar invested, the program facilitates a return to the United States' economy of US$500**.

The European Union is also moving towards implementation of a minor use program to assist its growers access necessary crop protection products.

An appropriately targeted, moderately funded minor use program in Australia can safeguard Australian agriculture by increasing its productivity and diversity. Ensuring that farmers have access to adequate crop protection technologies can also facilitate:

- Development of new industries growing new crops for domestic and overseas markets;
- Agricultural development of new regions for new crops as pest issues can be sustainably controlled; and
- Ongoing sustainable production within existing farming systems as new tools facilitate better, more effective and long-lived resistance management strategies.

  Critically, support for minor uses can reduce risks to users, consumers and the environment from off-label use. It will also minimise reliance on APVMA issued permits increasing its capacity to provide high quality risk assessments and registrations.

2. A new publicly funded program to clear the backlog of chemicals listed as a priority for review

CropLife notes that as part of the *Better Regulation of Agricultural and Veterinary Chemicals* reforms which are currently before the Parliament, a new and unnecessary regulatory process to identify and reconsider active constituents and chemical products is being proposed. However, there are already over 60 different active constituents that have been nominated for, or are currently under, review. Adding an additional, arbitrary time based, unnecessary registration review process on top of the current model would only add significant administrative work load to the APVMA and redirect resources away from the target review process while not providing any public benefit.

Once an active constituent comes under review, approval holders and product registrants are invited to engage and contribute to the review. This engagement is time consuming and costly. Often a chemical review process will also require approval holders and registrants to develop new data sets to demonstrate that a newly identified risk is acceptable, negligible or non-existent.

Registrants and approval holders therefore already make significant contributions to the chemical review program. Not only do registrants pay to develop the data sets to be assessed by the APVMA, but the sales levy paid on all product also funds the chemical review program.

The APVMA's chemical review program may receive more product nominations under the *Better Regulation* continuation application process. Without the resources to improve the capacity of the APVMA to conduct chemical review, this will simply add to the existing backlog without any improvement in the safety of the chemical portfolio managed by the APVMA.

A greater public funding contribution to the APVMA's capacity to review chemicals will demonstrate the importance of addressing the existing chemical review priorities before adding additional chemicals or products to the existing backlog.

3. CropLife suggests that Australia's regulatory system may also benefit from a greater financial contribution from public sources

Currently, the cost of the APVMA is almost entirely met through application fees and levies recovered from applicants and registrants of agricultural and veterinary products. This has led to some public criticism that agricultural chemical manufacturers have captured the APVMA, leading to perceptions that the decisions of the APVMA are not independent and expose the users, consumers and the environment to excessive risks from chemical use.

CropLife does not accept the contention that the current cost recovery arrangements result in any compromise of the integrity or independence of the regulator or the decisions that it makes. CropLife accepts that cost recovery is an important and appropriate tool to recover the costs associated with the APVMA's risk assessment and registration functions. That stated, CropLife accepts that an equally strong and valid argument might be made for the APVMA to be fully funded though general revenue.

While CropLife accepts the need for cost recovery, different elements of the APVMA's functions may be considered separately. CropLife does consider that there may well be a difference between the registration and assessment functions of the APVMA and the monitoring, compliance and enforcement functions. The significant public benefit enjoyed by consumers and the environment from assurance about the safety, quality and integrity of the regulatory system justifies consideration of the appropriate level of public funding.

Currently, in addition to funding the regulatory scheme for agricultural chemicals, CropLife and its member companies contribute to, and support a range of other stewardship programs that support the safe, sustainable and responsible transport, handling and use of agricultural chemicals. Our ***drum****MUSTER* and ChemClear® programs are world leading initiatives to responsibly deal with waste containers and chemical products. Our resistance management strategies support the effective responsible use of chemical products to delay and prevent the development of pest and weed resistance. Our accreditation and training program also ensures that facilities that handle and store agricultural chemical products are compliant with all Commonwealth, state and territory legislative requirements. These activities minimise the burden on jurisdictions to enforce their legislation.

Collectively, CropLife members contribute $13 million each year to stewardship activities that reduce the risk from agricultural chemicals throughout their lifecycle. Other parts of the crop protection sector contribute another $3 million, totalling $16 million from industry each year.

The APVMA's monitoring, compliance and enforcement activities are critical to supporting and maintaining the integrity of the current regulatory system. Maintaining this integrity does require that the APVMA take a broad approach to monitoring and compliance. The APVMA must not only focus on product registrants and approval holders, but manufacturers and importers that deliberately seek to avoid Australia's regulatory system.

Publicly funding monitoring, compliance and enforcement activities of pesticides will offer significant benefits to governments, industry and the community. It will:

- Ensure that the magnitude and scope of compliance and enforcement activities can be effectively matched to the size of the problem. It need not be restrained by the APVMA's limited budget;
- Demonstrate that registrants and approval holders have not captured the regulator and increase public perception of an independent compliance function;
- Address current inequity where the APVMA provides resources to identify non-compliance, gather evidence and conduct prosecutions, but is not able to access the proceeds from any fines imposed. Under the *Better Regulation* package of reforms, introduction of more extensive civil penalty provisions may result in a greater reliance on fines for legislative breaches; and
- Facilitate greater voluntary stewardship initiatives by industry to support government compliance functions.

CropLife considers that an appropriately funded regulatory scheme should reflect the commitment of all interested to enforcing the regulatory scheme. Increasing the public resourcing for compliance and enforcement would represent a significant increase in the Government's commitment.

Alternatively, comprehensive public funding for the APVMA would lead to a much greater perception that the APVMA was independent of any inappropriate influence by industry. Comprehensive public funding would also significantly reduce barriers to market entry for smaller registrants and facilitate the deployment of new products by small and medium businesses tailored for smaller crops and industries.

Attachment B outlines expected costs associated with these proposals.

CONCLUSION

Australia's farming sector, agricultural competiveness and the broader economy would benefit from a greater public funding contribution to the agricultural chemicals regulatory system. A moderate, specific and targeted program of investment has the potential to significantly improve Australia's agricultural productivity through continued innovation and development of plant protection products for minor and emerging industries.

Specific investments in monitoring, compliance and enforcement will also improve consumer perceptions regarding the independence of the APVMA. While CropLife does not accept the claims that the APVMA has been 'captured' by industry, specific investments to enhance the monitoring, compliance and enforcement functions of the APVMA would substantially address concerns regarding regulatory capture.

A program to no longer apply cost recovery to the APVMA would comprehensively address claims of regulatory capture. Provided that assurances regarding approval and registration performance were maintained, this alternative option would improve community faith in the independence of the APVMA as well as reducing barriers to Market entry for minor use products.

Providing additional funding to clear the backlog of current chemical reviews will provide additional assurance that the chemical products used in Australia are safe. It will provide an equitable and transparent base upon which a continuation application scheme can be introduced.

ATTACHMENT A

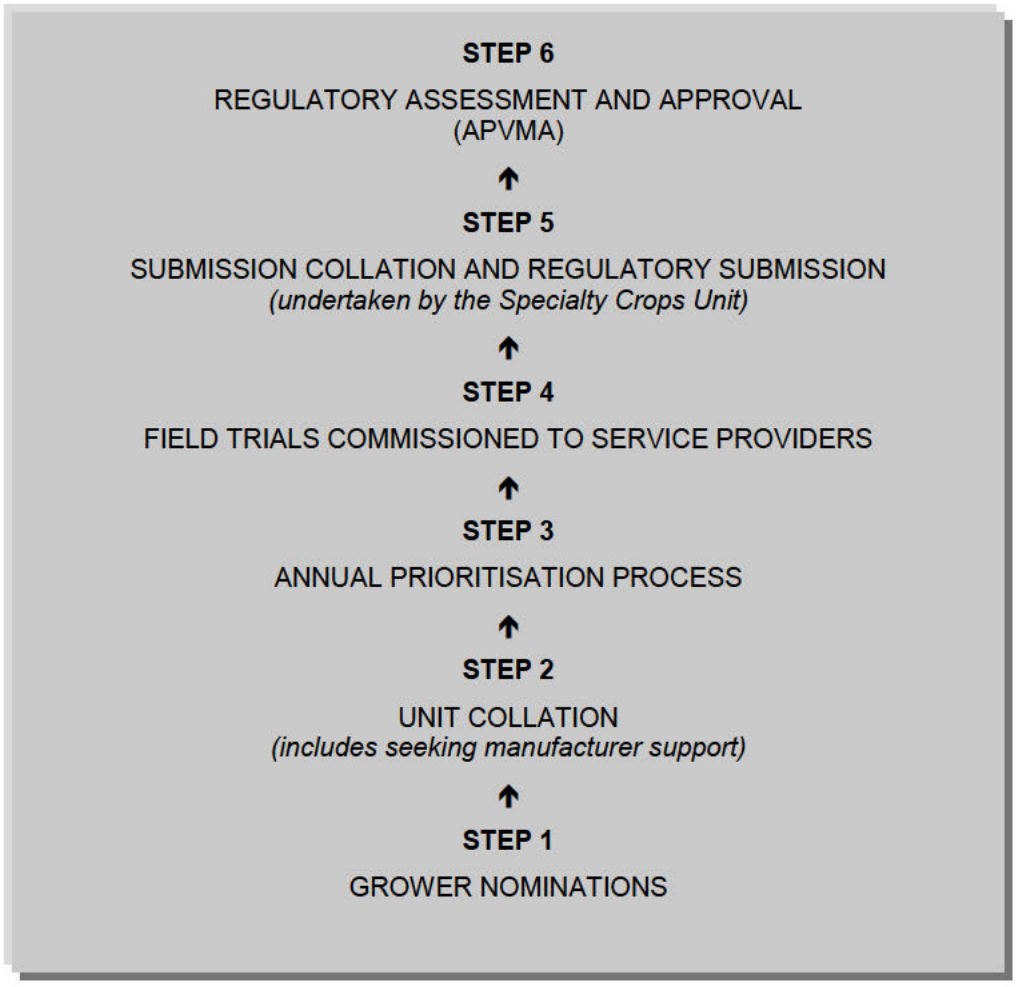
PROPOSAL FOR AUSTRALIAN MINOR USE PROGRAM

Australia can learn from minor use solutions that have been adopted in North America (eg. the IR-4 Project). It needs, however, to be remembered that the agricultural research infrastructure in Australia is different to that of the United States or Canada. For example, Australia does not have access to the Agricultural Research Stations that are active in the United States. On the other hand, Australia does have a range of agricultural Research and Development Corporations (RDCs) that perform similar research for many, but not all grower industries.

It is also important that any future approach in Australia is consistent with the strategic framework that was agreed between the states and the Federal Government in 2005.

Figure 1 below represents the proposed approach. Details on each step of the process follow.

FIGURE 1: AUSTRALIAN MINOR USE PROGRAM – PROPOSED PROCESS



STEP 1: GROWER NOMINATIONS

Growers will be responsible for identifying gaps in pest control options and submitting these to the Specialty Crops Unit (the Unit). There is a number of ways that this could be achieved:

1. Growers submit requests directly to the Unit.
2. Associations and relevant peak industry bodies submit a consolidated list of priorities to the Unit.
3. RDCs utilise their existing research priority setting processes to determine the priorities of the growers they represent.

STEP 2: UNIT COLLATION

If requests were made directly to the Unit then it would consolidate these into a single list and discuss with the relevant association, peak industry body and registrants. If there is a lack of support by the industry or the registrants, then the requests would not be progressed.

The Unit would also examine likely regulatory data requirements and associated costs, including the availability of existing supporting data both domestically and internationally (in potentially reducing local costs and fast tracking regulatory solutions).

If requests were made via an association or peak industry body, then the industry wide priorities would at that stage be developed and submitted to the Unit for collation. Similarly, if RDCs were the method for communicating priorities to a central unit, then these bodies could prioritise needs on an industry by industry basis.

STEP 3: ANNUAL PRIORITISATION PROCESS

The prioritisation process could involve an annual workshop where consolidated grower request lists are scored according to established criteria. The criteria for determining the higher priorities could include the following:

1. Funded projects maximise opportunities for crop group approvals.
2. The chemistry involved in the project is not a candidate for regulatory review and/or seeks to reduce risks posed by existing crop protection products.
3. The project addresses a need for pest control or enhances adoption of IPM.
4. The economic importance of the pest to the industry (relative to industry size).
5. The level of Unit funding that has already been allocated to an industry (ie. an equity principle).
6. The use has the support of a registrant to register the use.

Another option for allocating projects is on the basis of crop groups. This could take into account the number of representative trials required to gain a crop group approval, as well as the number of minor crops in a crop group. There could be different tiers of funding for different crop groups to ensure this is considered.

STEP 4: FIELD TRIALS COMMISSIONED TO SERVICE PROVIDERS

The Unit will negotiate the contract for undertaking the research trials each year. The trials will be undertaken by the accredited service provider that is most competitive in respect of quality, capacity and price.

Commissioned trials would involve a mix of both efficacy/crop safety and residue trials. The following principles could underpin the contracting of research trials:

- *Maximum contract size*

  Given the amount of research that could be contracted by the Unit, the negotiation of large contracts, rather than a series of small contracts, would seem sensible. If a number of different bodies were simultaneously seeking to contract the work, then the cost of each trial is likely to be increased as a result of the increased demand. The negotiation of larger contracts would, however, allow the Unit to be seen as a major contract annually for which different research providers would compete.

- *Good Laboratory Practice*

  Residue trials should be conducted in accordance with Good Laboratory Practice (GLP). This is the standard of data required for the Australian Pesticides and Veterinary Medicines Association's (APVMA) submissions and international data sharing, as well as establishment of Maximum Residue Limits in overseas markets, which are considered important aspects to the potentially broader international objectives of the Unit and regulatory outcomes.

  This component is not negotiable so all bids for the annual contract will need to be submitted by GLP accredited facilities.

STEP 5: SUBMISSION, COLLATION AND REGULATORY SUBMISSION BY THE UNIT

It is proposed that regulatory submissions would be prepared by the Unit. It is important that a single body is responsible for writing regulatory submissions as this would ensure they are of a suitable and consistent quality, as well as ensuring adequate reporting for the Unit's deliverables. This approach has been shown to be effective in both the United States and Canada.

Once a research project is completed, the scientific data would be submitted to the Unit by the service provider. The Unit would then use this information to construct a regulatory submission and submit this to either the registrant(s) or directly to the APVMA for regulatory assessment (with any associated fees).

STEP 6: REGULATORY ASSESSMENT AND APPROVAL

The APVMA will assess the submissions for regulatory approval according to the same criteria as other registration applications and the use would normally be one that would be approved as an on-label use, rather than off-label permit mechanisms.

The Unit (or the partner registrants) would pay the registration fees for the application, which would ensure that the APVMA has sufficient resources to promptly progress the applications.

OTHER ELEMENTS OF THE PROPOSED UNIT

- *Registering long-standing permits*

  During the first two years of the Unit's operation it is not expected that there will be many results from commissioned trials available for regulatory approval, due to the time taken to run the trials, analyse samples and submit results.

  In this period, the Unit will concentrate on registering long-standing permits that do not have outstanding data requirements, in cooperation with state government evaluators and/or partner registrants.

- *Gap analyses*

  Every 3-4 years each industry would perform a gap analysis that would examine which plant pests and which control tools are priorities for that industry. The gap analysis would be incorporated into the industry strategic plan. Lower risk products would be prioritised for future work. In time, this approach would provide the basis for prioritisation of projects undertaken by the Unit.

  In order to ensure that industries perform this task, it is proposed that from Year 4 of the program, any industry that could not show a strategic need for a pest control would not be able to access funding through the program. The implementation of this requirement has been postponed until Year 4 to allow all industries the opportunity to complete this analysis.

- *Reduced risk pesticides*

  Since 2000, over 80% of IR-4's research has involved new pest management technology with biopesticides and reduced risk chemistries. This focus on reduced risk compounds was achieved by a three pronged approach consisting of partnering with the agricultural chemical companies, educating specialty crop stakeholders and partnering with the Environmental Protection Agency to facilitate specialty crop registrations.

  A component of an Australian program would be dedicated to researching biopesticides and biological methods for controlling pests in various crops. These control measures can be used in conjunction with more traditional chemical control methods to address restrictions on withholding periods and re-entry intervals.

  It is proposed that one of the criteria to be used to determine funding for projects will be the use of reduced risk chemistry. An exception to this criteria would only occur when there were no effective reduced risk chemistries available for the proposed use pattern.

- *Priority Data Projects*

  Increasingly, certain broadly used chemicals have been subjected to regulatory reviews and use restrictions. Owing to a number of factors, these chemicals are often disproportionately important to specialty growers. It is therefore important that a national minor use program assist these industries in finding suitable and cost-effective replacements.

- *International Collaborations*

  As noted at *Minor Use 07*, international collaboration offers huge opportunities for reducing costs of regulatory approvals for specialty crops. In particular, joint projects with the United States and Canada provide real opportunities for work and data sharing. Cost reductions result from the reduction in the time and extent of trial work that needs to be conducted domestically.

  It is proposed that the Unit would have a specific budget for conducting joint trials with other international minor use programs. This would initially equate to around three projects per year. As confidence between the different national programs increases, the number of joint projects would also be likely to increase.

- *Communication*

  It is important that an initiative of this size has a communications strategy to ensure the numerous and diverse stakeholder industries are all aware of what the Unit can offer. This would be based on the strategy developed by the Minor Use Taskforce in 2005.

ATTACHMENT B
EXPECTED COSTS

(All figures in million dollars)

Proposal 1: National Minor Use Program

Year	2013/14	2014/15	2015/16	2016/17	2017/18
Annual Co	1.5	3.5	5	5	5
Total: $20.0					

Project 2: Chemical Review Clearance

Year	2013/14	2014/15	2015/16	2016/17	2017/18
Annual Co	2.4	3.6	4.8	4.8	4.8
Total: $20.4					

(Costs based on current AERP and CRP costs in December 2011 Cost Recovery Discussion Paper. $2.4m permits 5 reviews to be concluded each year. $4.8m should permit all outstanding high-priority reviews to be completed within the next 5 years (from 2014/15 at a rate of 10 per year. Some gradual ramp up will be required to permit registrants time to develop additional data if required.)

Project 3a: Compliance, Investigation and Enforcement and Information activities.

Year	2013/14	2014/15	2015/16	2016/17	2017/18
Annual Co	2.375	2.375	2.375	2.375	2.375
Total: $11.875					

(Costs based on current costs of HGP scheme, AgQA and investigation and enforcement costs contained in the December 2012 Cost Recovery Discussion Paper)

Project 3b: Public funding of the APVMA

Year	2013/14	2014/15	2015/16	2016/17	2017/18
Annual Co	32.8	34.4	32.9	32.9	32.9
Total: $165.9					

(Costs based on expected expenditure as outlined in the APVMA's December 2012 Cost Recovery Discussion Paper)