CropLife AUSTRALIA

SUBMISSION TO

EXPOSURE DRAFT
AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT BILL 2011

29 February 2012

CropLife Australia Limited
ABN 29 008 579 048
Level 2 AMP Building
1 Hobart Place Canberra ACT 2600
Locked Bag 916 Canberra ACT 2601

Tel 02 6230 6399
Fax 02 6230 6355
www.croplifeaustralia.org.au
Twitter: @CropOLifeOZ

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, formulators and registrants 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 essential to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $1.5 billion per year to the Australian economy and directly employs thousands of people across the country.

CropLife member companies spend more than $13 million a year on stewardship activities to ensure the safe use of their products on the environment and human health. CropLife ensures the responsible use of these products through its 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 members' 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 the coming decades. Each of these products is rigorously assessed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) to ensure they present no unacceptable risk to users, consumers or the environment. Without access to these tools, farmers may potentially lose as much as 50% of their annual production to pests and weeds.

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.

The Agricultural and Veterinary Chemicals Code Act 1994 is the primary Act regulating agricultural chemicals in Australia. As a result CropLife and our members have a strong interest in any changes. On this basis, CropLife cautiously welcomes the *Better Regulation of Agricultural and Veterinary Chemicals* process as it aims 'to cut red tape and increase the efficiency and effectiveness of agricultural and veterinary (agvet) chemicals regulation'[1]. Our members have long sought greater efficiency within the APVMA. We do, however, remain concerned that the reforms proposed will not deliver any greater efficiency and may ultimately result in poorer APVMA performance as it is required to undertake additional functions and provide new services that do not result in better protection of human health or the environment.

CropLife members are concerned that increasing the regulatory burden on industry will increase the total administrative and regulatory costs of the registration system, which may result in a loss of safe and useful products that will limit the number of agricultural chemistry tools available to farmers to control pests, weeds and diseases. CropLife is concerned that the promise of a more efficient regulator is merely a cover for a political policy agenda that is demonstrably unnecessary and ineffective.

The consequences of increasing the regulatory burden are significant. Excessive and inappropriate regulation will:

- Delay introduction of newer, modern agricultural chemicals for use by Australian farmers;
- Increase the costs of a key input of farm input, with corresponding flow on impacts through the supply chain; and
- Increase risks that demonstrably safe and effective chemicals are withdrawn from the Australian market.

[1] http://www.maff.gov.au/media_office/media_releases/media_releases/2011/november/reforms-a-boost-for-agriculture-and-veterinary-chemicals

Access to fewer tools can facilitate faster development of resistance among target pests, diminishing the usefulness of remaining chemical options. The economic impact of weeds on Australian agriculture is estimated to be in excess of $4 billion each year. The economic impact of weeds in Australia's native habitats is thought to be similar in magnitude[2]. In addition to the direct impacts on Australian agriculture and the environment, the responsible use of agricultural chemicals generates direct benefits for consumers. In the United States, it is estimated that modern crop protection chemicals have helped reduce by 40% the cost to consumers of fresh fruit and vegetables. CropLife expects consumer benefits to be of a similar magnitude in Australia.

A greater regulatory burden acts as a significant disincentive for introducing newer, better targeted and safer products. In some circumstances, a decline in availability of safe and effective control options can result in perverse environmental outcomes, driving farmers to use alternative weed control procedures that have a greater net environmental impact.

CropLife shares concerns expressed by several farmer associations that the reforms proposed under *Better Regulation* may selectively remove cheaper generic products where there is no incentive to generate additional data to support a registration. There remains potential for significant economic impacts from the loss of key chemistries for all farming systems.

Agricultural chemicals are a core input for modern farming systems. They represent a cost effective tool that farmers can use to control pests, weeds and diseases - and consequentially increase yields. Increasing costs to farmers at the beginning of the food supply chain will have significant, unintended impacts. Farmers cannot always pass increases in costs to markets, leading to risks that cost increases may in turn lead to whole farming sectors becoming no longer profitable.

Australia remains fortunate that it has some of the most advanced mechanisms to manage pest resistance in the world, which forms a core component of Integrated Pest Management Systems adopted by farmers across Australia. These systems rely on a range of available tools to prevent and delay resistance problems. The loss of even minor chemicals can lead to major impacts where that loss undermines the utility of existing resistance management guidelines.

This submission seeks to highlight those areas of the proposal where inefficiency remains and should be addressed by the *Better Regulation* proposals. It also seeks to identify areas where the existing proposals will increase regulatory burdens without providing any corresponding improvement in human health or environmental outcomes. CropLife also proposes targeted amendments to the exposure draft legislation that may minimise impacts on registrants and maximise the benefits of the proposed reform.

CropLife reserves the right to change the positions expressed in this submission or add further commentary should additional information and documents (such as supporting regulations and the risk framework) alter the likely impact on the agricultural chemical industry.

CropLife continues to look forward to working cooperatively with the Government to ensure that the objectives of the *Better Regulation* process are met.

[2] Australian Weeds Strategy – A national strategy for weed management in Australia. National Resource management Ministerial Council (2006), Australian Government Department of the Environment and Water Resources, Canberra ACT.

Summary of Recommendations

Recommendation 1: *Introduction of the package of reforms should be delayed while critical additional documents are made available for consultation.*

Recommendation 2: *All proposals should be assessed to identify the magnitude and scope of the problem being addressed, the reduction in risk resulting from the measures proposed and the case for government action.*

Recommendation 3: *The continuation application scheme must be assessed against Council of Australian Governments' Best Practice Regulation Principles to ensure that it is the most cost effective means of delivering improvements in human health and environment protection.*

Recommendation 4: *The impact of implementing reforms by the APVMA on the core business of assessing applications for registration should be identified prior to commencement.*

Recommendation 5: *The costs and benefits of each reform should be identified to ensure that a net benefit to the Australian community (including product registrants) is delivered.*

Recommendation 6: *New cost recovery arrangements should not commence in advance of a more comprehensive consideration of cost recovery policy for the APVMA.*

Recommendation 7: *Cost recovery modelling should be undertaken to identify public policy outcomes that maximise net community benefit from cost recovery options.*

Recommendation 8: *New cost recovery policies must remedy existing cross-subsidies, over recovery and ensure that public good activities are funded in accordance with the Australian Government's Cost Recovery Guidelines.*

Recommendation 9: *Measures to restrict flexibility to rectify applications must not commence until a comprehensive risk framework is in place.*

Recommendation 10: *An appropriate offset or additional extended data protection period should be provided for registrants of products protected by patent to reflect the loss of patent value as a result of the mandatory pre-market registration system.*

Recommendation 11: *The Government must consider additional reforms to improve the efficiency of agricultural chemical regulation to ensure that the total package of reforms delivers a net efficiency gain to the registration system.*

Recommendation 12: *The APVMA should prepare additional guidance to inform applicants about when trade and efficacy data will be required.*

Recommendation 13: *The proposal for a continuation application scheme be removed from the package of reforms.*

Recommendation 14: *A continuation application scheme should not commence until a risk framework is in place that provides certainty around how continuation applications will be assessed.*

Recommendation 15: *Approvals and registrations should be prioritised for reconsideration according to the date of first approval or registration rather than by using any hazard based criteria.*

Recommendation 16: *Continuation applications should be able to be made up until the day before a registration or approval expires.*

Recommendation 17: *The APVMA should be required to provide advice to approval holders or registrants about the need to make continuation applications at least three months before expiry.*

Recommendation 18: *Additional consideration should be given about how generic products that may not have access to conditions of approval or registration should be handled by a continuation process.*

Recommendation 19: *A strictly limited opportunity to rectify applications in some circumstances after the application has been accepted by the APVMA should be permitted to provide some flexibility.*

Recommendation 20: *Measures to restrict flexibility of the current system should only occur after comprehensive risk frameworks have been developed, providing greater clarity and certainty for applicants.*

Process, Timelines and Consultation

CropLife is concerned that there are significant gaps and shortcomings in the policy development process to date that has corrupted undermined the integrity and efficacy of the proposals now being put forward by the Government. These shortcomings are evidenced in incomplete, inconsistent and varying documentation presented to stakeholders for consultation. Further, CropLife notes that some consultation documents do not appear to comply with the corresponding Australian Government guidelines. In particular, neither the Regulation Impact Statement nor the Cost Recovery Discussion Paper complies with government guidelines for the development of Regulation Impact Statements or Cost Recovery Impact Statements.

CropLife understands that the *Better Regulation* proposals form part of a comprehensive suite of amendments. They include measures that are intended to improve the regulatory efficiency of the APVMA, create greater incentives for innovative industries to develop and register safer and softer crop protection technologies and to address some perceived gaps within the current regulatory structure of the Agricultural and Veterinary Chemicals Code. However, many of the reforms designed to improve the efficiency of the regulatory scheme will not achieve their objective and could potentially result in greater overall inefficiency. In particular, new processes and requirements for periodically sun-setting registrations as part of a new continuation application, or reregistration, scheme will increase costs to registrants. If this results in the loss of safe, effective and useful chemicals from the market, the potential impact on farmers from losing pest and weed control tools could be economically significant. Losing access to products can accelerate resistance among target pests and diminish the effectiveness of remaining products.

CropLife is disappointed that the apparent efficiency measures contained within the *Better Regulation* package of reforms seek to merely reduce the risk of the APVMA not providing decisions on applications within the required timeframe by increasing the risk that registrants will not be able to provide applications that meet all APVMA requirements. This does not increase the efficiency of the system, but merely seeks to transfer responsibility for the APVMA's performance from the regulator to applicants. Genuine improvements in efficiency would see reductions in the burden of regulatory compliance across the entire registration process.

CropLife can only support the package of amendments in circumstances where the cost of additional requirements is outweighed by the improvements in efficiency and cost from reductions in the regulatory burden. Our investigations into this proposal to date have indicated that this condition will not be met.

Analysis of the exposure draft legislation has been hampered by inconsistent and missing elements. Currently the Regulation Impact Statement contains no information regarding the expected costs and benefits associated with any of the proposed reforms, instead relying on assertion and simplistic qualitative analysis to estimate regulatory impact. There is very little information to confirm that the reforms will result in a net benefit to registrants and applicants. Inconsistencies between the Regulation Impact Statement and the draft exposure legislation make efforts to analyse the impact on the agricultural chemical industry difficult.

Analysis is further hampered by other critical documents that are currently not available. Changes to regulations under the Agricultural and Veterinary Chemicals Code Act 1994 that will be necessary are not available for comment. The risk framework that will need to underpin the push for enhanced information flow between the regulator and applicants is only in its infancy. Without these documents, CropLife remains suspicious of any claims of genuine benefits for our members.

It is disappointing that the Government also did not release documents such as the Activity Based Costing Assessment conducted by PricewaterhouseCoopers or the Service Level Arrangements (SLAs) between the Department of Health and Ageing (DOHA), the Department of Sustainability, Environment, Water, Population and Communities (SEWPAC) and the APVMA. These documents would assist industry and the broader community give an in-depth consideration to proposed efficiency improvements. The DOHA and SEWPAC SLAs are core to the efficient performance of the registration system and their availability would have contributed to stakeholders being able to provide further suggestions for additional efficiencies in the system. Furthermore, not releasing these documents is at odds with the stated principles of the Government's own policies regarding access to information.

CROPLIFE STRONGLY RECOMMENDS that any Bill's introduction should only occur after critical underpinning documents can be prepared in collaboration and consultation with all affected stakeholders. These reforms represent the most significant and potentially beneficial changes to Australia's regulatory system for agricultural chemicals in 20 years. It is critically important that the Government take the necessary time to get these reforms right, rather than to meet an arbitrary deadline.

Extending the timeframe for development and implementation of these reforms will allow the Government to develop and consult on potential regulations and comprehensive risk frameworks, as well as allow it to fully consider the comments made during this consultation process. Taking this extra time will assist the Government in fine tuning the appropriate regulatory settings and provide confidence to stakeholders that the concerns being raised through this current process are being addressed.

> ***Recommendation 1:***
> *Introduction of the package of reforms should be delayed while critical additional documents are made available for consultation.*

COAG Principles

CropLife remains concerned that none of the documentation that has been issued by the Government indicates how these reforms are compliant with the *COAG Principles of Best Practice Regulation*[3]. In some respects, elements of best practice regulation have been considered, but this has not occurred in a coherent nor logical way. As a consequence, many of the reforms are not well targeted to the problems that are sought to be addressed and will only serve to exacerbate existing timeliness and efficiency concerns. This is demonstrated by the fact that the expected cost of the new efficiency reforms will add $9m to the costs recovered from industry each year.

This problem again highlights the core concern that the policy responses proposed to address identified problems do not appear to be linked in any rational or meaningful way. This is particularly the case when considering the consultation process to date in the development of a policy for continuing approvals and registrations. This process falls well short of the standards set by COAG. Several principles designed to ensure that regulation is only imposed where necessary, relevant and efficient have not been complied with. For example:

Principle 1: Establishing a case for action before addressing a problem. Establishing a case for action involves several steps and must:

- Present evidence of the magnitude (scale and scope) of the problem;
- Where the problem involves risk, identify the relevant risk and estimate the probability of an adverse outcome; and
- Present a clear case for considering that additional government action may be warranted.

To date, no evidence of the magnitude of the problem has been presented, nor has any estimate of the probability of adverse outcome been made, and without these elements, no clear case can be made to justify additional government action. So far, the problem expressed by the Government is that there is no reregistration scheme requiring registrants to regularly demonstrate that their products meet contemporary standards.

Principle 2: A range of feasible policy options must be considered including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs considered.

As the Government has failed to adequately define the problem, it is not able to adequately consider an appropriate range of options. Indeed the Regulation Impact Statement does not consider any non-regulatory, co-regulatory or self-regulatory options. All the options considered represent variants of the same option, which is to implement a regulatory reconsideration (continuation application) scheme.

Principle 3: Adopting the option that generates the greatest net benefit to the community.

Without a formal, quantitative assessment of the expected costs and benefits to industry, government and the community, there is no basis upon which to identify an option as having the greatest net benefit.

Principle 7: Consulting effectively with affected key stakeholders at all stages of the regulatory cycle.

To date, the consultation with affected industries has not been as effective as is necessary to deliver the real improved public policy and regulatory outcomes. Consultation has been hampered by inconsistent and incomplete documentation, as well as by different and shifting interpretation of key provisions of the exposure draft legislation. This significantly undermines the capacity for all stakeholders to provide genuine and useful feedback to the Government.

[3] http://www.finance.gov.au/obpr/docs/COAG_best_practice_guide_2007.pdf

CROPLIFE STRONGLY RECOMMENDS that the Government reconsider its proposals in the light of the COAG principles to ensure that the best outcomes for governments, communities and impacted industries are achieved.

CropLife does note the problems with APVMA efficiency that have been identified through the policy development process. However, the magnitude of the problem has not been identified, nor has there been a proper assessment of the costs and benefits associated with the efficiency reforms.

> ***Recommendation 2:***
> *All proposals should be assessed to identify the magnitude and scope of the problem being addressed, the reduction in risk resulting from the measures proposed and the case for government action.*
>
> ***Recommendation 3:***
> *The continuation application scheme must be assessed against Council of Australian Governments' Best Practice Regulation Principles to ensure that it is the most cost effective means of delivering improvements in human health and environment protection.*

Resourcing and cost recovery

CropLife remains disappointed that the Regulation Impact Statement makes very little reference to the expected costs and benefits of the proposed reform package. Without a clear understanding of the expected costs and anticipated savings and efficiencies, CropLife, and indeed other key stakeholders, cannot assess whether the potential benefits of efficiency improvements outweigh the increased inefficiency associated with the continuation application process. A comprehensive cost/benefit analysis of each of the current proposals is essential to understand the impact of these reforms on CropLife members. While an interim Cost Recovery Discussion Paper has been prepared by the APVMA, and this indicates that these new measures may require the APVMA to recover as much as an additional $8 million each year from registrants, this merely represents the total additional cost recovery from applicants and registrants rather than genuine additional cost of particular elements of reform.

The *Better Regulation* proposals will impose significant additional functions on the APVMA. CropLife would welcome greater assurance that the additional resources required to perform these new functions result in a net improvement in the APVMA's performance. Increasing efficiency should permit the APVMA to increase productivity, or enable it to perform at the same level with fewer resources.

Implementation of several *Better Regulation* proposals will also require the investment of resources at an early stage. Development of a comprehensive risk framework will require both technical and financial resources well before measures to limit the APVMA's flexibility in rectifying applications commence. Neither the Regulation Impact Statement nor the Cost Recovery Discussion Paper outline the potential impact that deployment of these resources will have on the APVMA's core business of assessing and registering chemical products.

> ***Recommendation 4:***
> *The impact of implementing reforms by the APVMA on the core business of assessing applications for registration should be identified prior to commencement.*
>
> ***Recommendation 5:***
> *The costs and benefits of each reform should be identified to ensure that a net benefit to the Australian community (including product registrants) is delivered.*

CropLife notes that the APVMA is separately conducting a process to consult on its Cost Recovery Discussion Paper that makes recommendations to fund its activities for the transitional period until new legislation is in place. While CropLife will be providing a separate submission in response to that discussion paper, there are important issues of cost recovery policy that are properly dealt with by the policy agency, in this case the Department of Agriculture, Fisheries and Forestry (DAFF).

Given the significance of the legislative changes that are being proposed, CropLife considers that it is important for the policy agency, DAFF, to conduct a more thorough consultation on cost recovery to ensure that the policy objectives sought to be achieved through cost recovery are still applicable. As the current process is designed to only ensure that the APVMA has adequate resources to fund its activities, it is insufficient as a consultative mechanism to discuss the applicability of cost recovery generally.

CropLife does question the approach employed by the APVMA to launch an interim cost recovery process in advance of a more comprehensive and formal review of cost recovery in 2012. The APVMA's process pre-empts this activity, potentially resulting in significant duplication of work and inefficient use of resources when a cost recovery review is imminent.

The current arrangements for cost recovery do result in several undesirable outcomes for approval holders and registrants. These include:

- **Funding some activities through cost recovery that may be more appropriately funded through general revenues.** The Australian Government Cost Recovery Guidelines[4] suggest that public goods, such as education and communication activities, and parliamentary servicing functions may be more appropriately funded **through** general revenues. Further, in the light of criticism that the APVMA has been 'captured' by the agricultural chemical industry, there may be benefits in the APVMA's monitoring, compliance and enforcement functions also being funded from general revenues.
- **Inappropriate cross-subsidisation of regulatory costs incurred by unsuccessful products by successful, high volume products** - Where products do not generate significant sales, the cost of registration may not be recovered by levy. This results in products with larger sales volumes subsidising the regulatory cost of these products.
- **Over-recovery of regulatory costs for some products -** An uncapped levy applied to the sales of all products results in significant over-recovery of regulatory cost for those products with large sales volumes.
- **Inability to consider alternative options for meeting cost recovery objectives.** To date, there has been no consideration as to whether alternative models for cost recovery might better achieve the policy objectives sought, at a lower cost to industry.

These issues need to be addressed through comprehensive reconsideration of APVMA cost recovery from a policy perspective.

Recommendation 6:
New cost recovery arrangements should not commence in advance of a more comprehensive consideration of cost recovery policy for the APVMA.

Recommendation 7:
Cost recovery modelling should be undertaken to identify public policy outcomes that maximise the net community benefit from cost recovery options.

Recommendation 8:
New cost recovery policies must remedy existing cross-subsidies, over recovery and ensure that public good activities are funded in accordance with the Australian Government's Cost Recovery Guidelines.

[4] http://www.finance.gov.au/publications/finance-circulars/2005/docs/Cost_Recovery_Guidelines.pdf

Links to other reform processes

CropLife notes that there are other reform activities that will also have a direct impact upon the agricultural chemicals industry. Efforts by the Commonwealth, states and territories to establish a nationally consistent mechanism for the control of use of agricultural chemical products will result in significant impacts upon the national registration scheme. Ideally, this activity and the Commonwealth's *Better Regulation* processes would be linked to ensure that the overall outcome from both processes results in a net improvement to the system for regulating agricultural chemicals in Australia.

Implementation timeframes

CropLife notes that many of the reforms proposed are reliant upon the introduction of a comprehensive risk framework. This includes introduction of the continuation application process as well as many of the proposed efficiency reforms. CropLife expects the comprehensive risk framework to outline how the APVMA assesses applications to provide much greater certainty to applicants that they are providing complete applications that can be rapidly processed.

Where reforms rely on the implementation of the risk framework, reforms should not commence until after the framework has been put in place. CropLife is concerned that the current implementation schedules do not allow sufficient time for the development of the risk framework.

Without this framework, many of the efficiency reforms proposed will not achieve their objective. Rather than improving efficiency, many applications may be improperly refused with applicants forced to resubmit and draw upon additional assessment resources.

> ***Recommendation 9:***
> *Measures to restrict flexibility to rectify applications must not commence until a comprehensive risk framework is in place.*

General Comments on the regulatory system

Approaches to Risk, Hazard and Precaution

CropLife supports the APVMA's current approach to managing the risk associated with agricultural chemical products and notes that the exposure draft legislation does not propose to make changes to the APVMA's basis for science-based decision making. Decision making that is based on high quality science ensures that reliable, predictable decisions are made that provide assurance that users, consumers and the environment are protected when registered products are used in accordance with label directions. Other stakeholders have suggested that the APVMA should make some key changes to its approach to risk to include peculiar interpretations of the Precautionary Principle, or to adopt particular hazard-based elements of some overseas (particularly European) regulatory systems.

CropLife does not support approaches to regulation that seek to prohibit products following a simplistic consideration of the hazards associated with an active constituent as proposed by some commentators. While CropLife understands that the intention of many proposals to adopt hazard based restrictions in Australia, this is unlikely to generate any significant improvement in human health or environmental protection and may indeed result in perverse outcomes. CropLife supports the current approach where the risk of the formulated product is assessed taking into account all the appropriate instructions and restraints necessary to ensure that any genuine risk remains acceptable.

Employing artificial hazard based restrictions on products may ultimately result in poorer outcomes for farmers and the environment. For example, products can be formulated so that the intrinsic hazards of a product are controlled to the point that they present little more than a remote, or negligible, risk. For example, products that present a hazard through inhalation toxicity may be formulated into granular products that cannot be inhaled. To restrict products on the basis of intrinsic hazard may result in safe, effective and reliable chemicals being lost from the Australian market.

CropLife also notes that proponents of the Precautionary Principle in regulatory decision making often misconstrue its content, ignoring economic elements that form part of most constructions, including that expressed at the 1992 Rio World Summit. CropLife does not support the Precautionary Principle as a sound basis for regulatory decision making on the basis that its content is uncertain and it is often incorrectly called upon to support regulatory action that is not justified by a proper understanding of the genuine risk presented by any particular product. CropLife does support an appropriate level of caution in regulating agricultural chemicals and notes that the APVMA's current approach means that chemicals can only be approved and products registered for use in circumstances where the applicant has demonstrated that they can be used safely. This facilitates farmers' access to a wider range of tools while still ensuring that approved and authorised products are safe when used responsibly and lawfully.

The approach also, appropriately, places an onus upon applicants to demonstrate to the APVMA that chemicals and products can be used safely.

CropLife does note that during several consultations, some participants expressed a desire for a system that would seek to prohibit chemicals where significant regulatory action has occurred overseas. CropLife does not support these proposals as they generally rely upon inaccurate presumptions and logically flawed reasoning. For example, several organisations have compared the availability of chemicals in Australia with that available in Europe and assumed that the only reason for any difference between the two is due to more advanced human health and environmental protection systems employed in Europe. This is inaccurate as there is a range of reasons why the chemical inventory will be different in Australia. These include:

- **Different crops and agricultural systems:** Australian agriculture is markedly different to European systems. We also grow different crops in different ways. This means the exposure to chemicals is different, and may result in an acceptable exposure in Australia, but not in other countries;

- **Different environment:** Australia's lower rainfall, higher temperatures and unique plants and animals mean that we have different sensitivities to different chemicals. This sometimes means that chemicals used overseas are not permitted in Australia
- **Different markets:** Companies themselves market a range of products and these can replace older chemistries that become redundant and are removed for commercial reasons, rather than because of any concern for human health or the environment.
- **Use of arbitrary thresholds:** Other regulators (such as in the EU) impose arbitrary thresholds that make no allowance for risk. For example, European regulators impose a blanket 0.01ppb level for pesticide in ground water irrespective of whether that level results in an unacceptable risk.

Even where chemicals may be banned overseas because of a health concern, the same concerns may not specifically translate to the Australian context. Different demography, use patterns and exposures may mean that Australian use does not give rise to the same concern.

CropLife supports risk-based decision making that takes into account specific Australian circumstances. The regulator must be able to examine whether the risks that lead to further restrictions upon a chemical in another jurisdiction are applicable to Australia. Automatic systems that trigger formal chemical reviews after overseas regulatory action are not supported as these simply build in additional unnecessary cost. Australia's regulator must maintain the flexibility to only call chemical reviews at times where there are genuine concerns that are applicable to Australian circumstances.

Missing reforms

CropLife considered that there remain several areas of reform that could have been addressed through the *Better Regulation* proposals that are currently not included within the package of reforms. Many of these reforms have been discussed with the APVMA for several years and have not been progressed due to a lack of resources on the part of the APVMA. Others are now necessary as a result of subsequent changes to the Australian regulatory landscape. Genuine efficiency reforms that should be part of the reform process include:

- **Reducing the scope of products assessed by the APVMA.** Dairy sanitisers and swimming pool chemicals and cleaners may not fit within the regulatory scope of the APVMA and may be more appropriately regulated by another Commonwealth agency if necessary. Removing these products from the scope of the APVMA will enable it to focus its resources on its core business of assessing agricultural chemicals and veterinary medicines without diluting its resources into other areas.
- **Clarifying obligations regarding the export of agricultural chemicals exported under permit.** Currently, some chemical products are required to have an APVMA issued permit to be exported from Australian manufacturing sites. Permitted products are treated as being 'registered' for the purposes of the Agricultural and Veterinary Chemicals Code Act and are therefore subject to the sales levy. As the APVMA has practically no role in the assessment or compliance obligations associated with these products, collecting a sales levy is unnecessary. Amending the Code Act to correct this anomaly could easily be achieved through the current process.
- **Mechanisms to equitably deal with product spring boarding.** Spring boarding occurs when a registrant obtains a registration for a product prior to patent expiry. Putting mechanisms in place to recognise that spring boarding reduces the already diminished patent value that occurs as a need for pre-market approval of agricultural chemicals. Measures are in place in other Australian regulators, such as the Therapeutic Goods Administration to provide a minimum period of effective patent life to address the issue of spring boarding.
- **Mechanisms to facilitate participation by all registrants and/or approval holders to generate data for chemicals that are placed under review**. These include mechanisms to encourage all product registrants to participate in data generation activities at an early stage of the review process.
- **Circumstances where the APVMA can accept data assessments made overseas by comparable regulators without duplicating them in Australia**. This would allow the APVMA to concentrate on those elements of applications that may present unique Australian risks and risk management.
- **Disbanding the APVMA Advisory Board.** Currently, this Board serves no useful purpose yet drains the resources of the APVMA in providing fees and secretariat services. Its removal would free scarce APVMA resources for core activities.

Other reforms may need additional consideration but may ultimately be implemented as part of a concerted effort to improve the efficacy and effectiveness of the Australian regulatory system for agricultural chemicals. Such reforms may include:

- **Implementing an expanded scheme for classes of products of low regulatory concern**. While this may require some further consultation with affected industries, CropLife would welcome a discussion on whether certain criteria could be established to facilitate the registration of products that would not unreasonably be expected to generate unacceptable risks to users, consumers or the environment. Again, successful implementation of a reform of this type would enable the APVMA to focus its resources on agricultural chemicals that potentially present the greatest risks.
- **Implementing a program to actively support minor uses for agricultural chemicals.** While not strictly an efficiency reform, a program of this type will be critical to address some of the consequences from proposed reforms. At any one time, the APVMA may be processing as many as 1000 permits for minor uses. This puts a significant strain on scarce APVMA resources. A minor use program dedicated to developing data necessary to support getting new uses onto product labels would minimise the need for ongoing permits.

- **Providing for the APVMA to consider the net environmental impact associated with the removal of an agricultural chemical**. In some circumstances, cancellation of an active constituent approval or cancellation of a chemical product may have adverse environmental consequences. In some very limited circumstances this could be used to justify some use patterns to ensure the protection of Australian ecosystems.
- **Ensuring consistency among regulators with respect to workplace safety risks**. New national workplace legislation requires agricultural chemical users to conduct workplace risk assessments. The Government should consider whether changes to the APVMA's systems could be made to ensure that the APVMA's assessments continue to provide benefits to users.
- **Providing for the APVMA to competitively source health and environmental risk assessments**. Currently, these assessments are only conducted by the Department of Sustainability, Environment, Water, Population and Communities and the Department of Health and Ageing. Often these departments use contractors to conduct these risk assessments. Allowing the APVMA to directly contract with risk assessment providers could potentially save significant resources.

Each of these reforms represents an opportunity to reduce the red tape imposed on registrants of agricultural chemical products. Their successful implementation would increase the APVMA's efficiency and capability to deliver high quality risk assessments and registrations in a timely manner. Most of the reforms suggested here are not new and have previously been discussed with both the regulator and the Government. It is therefore disappointing that these potential reforms have been overlooked in favour of others (such as the continuation application scheme) that will increase the industry's regulatory burdens without any evidence of improved protection for human health and the environment.

Recommendation 10:
An appropriate offset or additional extended data protection period should be provided for registrants of products protected by patent to reflect the loss of patent value as a result of the mandatory pre-market registration system.

Recommendation 11:
The Government must consider additional reforms to improve the efficiency of agricultural chemical regulation to ensure that the total package of reforms delivers a net efficiency gain to the registration system.

Comments on Specific Schedules

Schedule 1 – Decision making using a risk-based framework

CropLife welcomes reforms that will improve the efficiency and transparency of decision making under the legislation by referencing an overarching risk assessment framework. It is expected that this will provide a comprehensive reference to the risk assessment process and improve the predictability of regulatory decisions.

To provide the necessary predictability, the comprehensive risk framework must provide potential applicants with clear guidance regarding:

- Application and data expectations of applicants;
- Risk assessment approaches and tools to be employed in assessing an application, including all assumptions used;
- Options available to applicants to mitigate the risk associated with a new product; and
- The steps evaluators will follow in evaluating the application.

CropLife understands that some of this information is currently available in the APVMA's Manual of Requirements and Guidelines (MORAG), however, applicants still face challenges in obtaining predictable decisions when all the necessary tools, presumptions and risk mitigation options are not fully communicated in advance of applications being made.

In order to deliver the predictability and certainty desired by registrants and applicants, the risk framework must be in place before applications under the new arrangement are made. Further, all evaluators (including those in external agencies such as the Department of Sustainability, Environment, Water, Population and Communities and the Department of Health and Ageing) must be required to rigorously adhere to the processes and requirements described in the framework. As indeed applicants are expected to.

CropLife is concerned that consultations have suggested that the current Environment Risk Manual may represent the template for development of other risk manuals. While the Environment Risk Manual is a useful document for registrants, it does still contain significant ambiguity and gaps that undermine predictability. All risk manuals must ultimately be owned and controlled by the APVMA to prevent external agencies from introducing new requirements without notification or adequate consultation with the affected industry. If the APVMA's external evaluators fail to conform to the risk framework developed by the APVMA, the value of the framework in delivering improved predictability and consistency will be significantly undermined.

CropLife also supports provisions to allow the APVMA to determine whether trade and efficacy data will be required for certain application proposals contained within Items 6, 7, 8 and 9 of *Schedule 1*. It is expected that this will deliver two distinct benefits for regulatory efficiency. For applications where trade and efficiency data is not considered relevant by the APVMA, applicants will benefit from not having to provide that data, reducing the cost of preparing applications for assessment. Additionally, by enabling the APVMA to focus its resources on relevant applications and risk assessments, all other applications have the potential to benefit as well.

However, CropLife would welcome additional information regarding when trade and efficacy data would be expected to be provided. This will assist potential applicants to be sure that they have provided all the necessary information supporting their application to the APVMA.

CropLife supports this as an important flexibility and efficiency reform that will permit the APVMA to match its regulatory effort to the risk associated with the product under assessment. It remains unnecessary for the APVMA to assess these elements for trade risk where none is present.

While for many products, this will have limited direct effect on CropLife members, there are likely to be benefits from minimising APVMA scrutiny and regulatory effort on issues and assessments that have limited value.

CropLife suggests that there may be other areas that the APVMA may contemplate not considering in applications. This should include a complete reassessment of the scope of products that fall within the responsibility of the regulator. Many consumer products that currently require registration and approval could be excised from the Agricultural and Veterinary Chemicals Code. This process should also recognise the role that other regulators have in regulating specific classes of products to ensure that the overall regulatory system is complementary rather than duplicative. For example, consumer products that currently fall within the scope of the Agricultural and Veterinary Chemicals Code are also regulated by the Australian Competition and Consumer Commission (ACCC). If it is more efficient for these products to be solely regulated by the ACCC, then this should be facilitated, and would enable the APVMA to focus on its core business of regulating agricultural and veterinary chemical products.

CropLife would welcome further discussion with the APVMA and DAFF on possible other areas where APVMA consideration may not be necessary for some classes of applications.

Recommendation 12:
The APVMA should prepare additional guidance to inform applicants about when trade and efficacy data will be required.

Schedule 2 – Continuation of approvals, registrations and listed registrations

CropLife is concerned that the proposals for continuation applications builds in another layer of bureaucracy without providing any meaningful improvement in human health, safety or environmental outcomes. This results from the significant disconnect between the policy objective of *Better Regulation* and the content of the exposure draft legislation. The problems identified in the Regulation Impact Statement issued with the exposure draft of the proposed legislation stated that:

> "While the APVMA's regulation of agvet chemicals is effective in protecting human health and safety; the environment and Australia's ability to trade its agricultural produce internationally… the system is not working as efficiently and effectively as it should"

CropLife agrees with the observation within the Regulation Impact Statement that agricultural chemical regulation is currently effective in protecting human health, safety and the environment. This view is shared by the Productivity Commission and the Australian National Audit Office, which have stated that:

> "(the APVMA) had reasonable arrangements for identifying an prioritising existing chemicals requiring review"

CropLife understands that there are problems associated with the APVMA's current Existing Chemical Review Program. These problems are demonstrated by the significant proportion of time that many chemicals spend under review, with chemicals averaging in excess of five years from commencement to conclusion of a review. The excessive time taken to complete some chemical reviews is sometimes due to structural elements that encourage registrants to delay and avoid participation in data generation activities. However, other causes such as the generation of poor quality research designed to target particular chemicals over a number of years also makes a significant contribution to long review timeframes.

Creating additional bureaucratic processes to sift and identify chemicals requiring review will not address the backlog of chemicals already identified unless there are genuine mechanisms in place to encourage all registrants with products affected by a chemical review to participate in generating any new data that may be required. The continuation application process may therefore result in safe and effective chemicals being cancelled where new data cannot be provided to support existing approvals and registrations.

It is concerning that the measures proposed are not targeted at addressing the core problems associated with the current chemical review program. Instead, by building in additional bureaucracy and inefficiency through an ill-considered process, there is likely to be less capacity for the APVMA to deliver timely, high quality chemical reviews.

Implementation of the continuation application process may simply result in a far greater number of chemicals being referred for review. While CropLife supports prompt and appropriate action by the APVMA when there is evidence that a particular risk is not being sufficiently controlled, there is already a significant backlog of chemicals currently awaiting review. Merely adding to this list will not result in any greater capacity for the APVMA to complete reviews.

Despite CropLife's concerns, there is a number of detail clarifications and amendments that will need to be taken into account before the legislation can be introduced.

Most importantly, commencement of continuation applications must only occur after a comprehensive risk management framework has been developed by the APVMA. This risk management framework will need to underpin the decisions made by the APVMA when considering what products and active constituents should be subjected to review. It will be critical in assisting registrants assess the potential costs associated with supporting a chemical through a review process. Without clear guidance on the potential need for new information, registrants may take a broad view with respect to the likely demand for new information and prematurely withdraw products because of anticipated additional regulatory costs.

The risk framework would also be used to determine the order of priority in which chemical products would be scheduled for continuation. CropLife understands that this will also mean that all products with the same active constituent will need to enter the continuation process at the same time to maintain market equity for competitive products. CropLife supports a risk-based approach to prioritising chemicals for continuation. Consultations to date have indicated that this could result in active constituents being prioritised according to the date of first approval on the basis that older approvals have had a longer time for specifications to drift from that approved by the APVMA. CropLife would support this approach. Proposals to prioritise active constituents according to their intrinsic hazard are not supported by CropLife.

CropLife accepts and agrees with the intention that all products with a common active should enter the continuation process at the same time. Measures will need to be in place to ensure that products that contain multiple active constituents are treated equitably and are not subjected to multiple continuation processes solely due to containing multiple active constituents. Products with multiple actives will proceed through the continuation process in line with the first of its actives, but will also have to be assessed on the potential for additional/reduced risk from the combination of actives at the same time.

The risk framework would also be expected to identify those circumstances where, as a consequence of a continuation application, a product and active have their registration continued for a period between seven and 15 years. It is anticipated that the risk assessment framework would assist in identifying when the outcome of a continuation application process would result in less than 15 years continued approval. CropLife is keen to continue to work with the APVMA to consider those applications and circumstances where a shorter period of continuation is appropriate. CropLife does note that continuation for a product for seven years more than doubles the regulatory cost when compared to a product that is continued for 15 years. The proposed legislation does not yet provide any information on how this might be justified other than through generic statements about basing continuation timeframes on risk. CropLife would be cautious to ensure that this process is transparent and accountable to ensure that products are not subjected to shorter approval periods without a clear justification on unambiguous and scientifically justified criteria. In the absence of any criteria, **CROPLIFE RECOMMENDS** that all approved products be continued for 15 years.

Greater clarity and certainty for these issues will be provided through implementation of the comprehensive risk framework. The greater detail provided by the risk framework will enable applicants, registrants and other stakeholders to understand the way that the APVMA identifies and manages the risks from agricultural chemicals. It will be critical in informing the business decisions of registrants to decide on whether to support a particular approval or registration through a continuation process. As a consequence, commencement of the continuation application scheme must not occur until the risk framework is established.

CropLife does note that the continuation approval framework does require the APVMA to continue approvals and registrations where it has ‘no reason to doubt’ whether the continued use of a chemical product would result in unacceptable risks to safety, health, the environment or trade. CropLife supports the adoption of this new test and notes that it does require the APVMA to actively identify a reason for referring a product for review.

During DAFF’s consultations, some stakeholders expressed concern that the new test inappropriately places the onus on the APVMA to identify problems, rather than requiring approval holders and products registrants to demonstrate that their products remain safe. This position ignores that:

- Approval holders and product registrants have already demonstrated the safety of their products at the time of registration. At that time, registrants have developed data to demonstrate that safety to an independent regulator.
- If the same test for registration was applied for continuation applications as for approvals and registrations, organisations and registrants making continuation applications would simply resubmit the same package of information previously submitted in support of the original application. Unless the APVMA identifies new concerns, an applicant could reasonably suspect the APVMA to make the same decision on the same information previously presented to it. This would not be an efficient use of resources for either the APVMA or continuation applicants.

- If approval holders and registrants are going to be required to submit additional data, they need to know what specific risks the requested data is expected to address. Unless the APVMA can identify a specific new risk that it has not previously considered, reapplying the same test as a new product will not give any information about how the APVMA would be satisfied about product safety.
- The APVMA already has access to a range of information that might raise concerns regarding the ongoing safety of a product. The Adverse Experience Reporting Program, National Residues Survey and self-reporting obligations on registrants and approval holders under s161 does enable the APVMA to identify potential risks from products that may inform a decision under a continuation application.
- If an active constituent or a product has already been registered in other jurisdictions and used safely for many years without any reported concerns, then that would tend to support the continued use of the active or product. In the absence of genuine new concerns about the safety of an active or product, a history of safe use should allow the APVMA to grant a continuation application.

CropLife does offer the following comments regarding specific issues and amendments that should be addressed before the continuation scheme commences:

- Confirmation that all actives and products containing the same active must be subject to continuation applications at the same time. This will prevent advantages or disadvantages being provided to registrants marketing competitive products resulting from differences in reconsideration scheduling.
- For Items 6 and 7, where the APVMA considers that a continuation application presents no unacceptable risks to users, consumers or the environment, the APVMA should approve the continued registration or approval of that product for a fixed 15 year period. Once satisfied that the active constituent or product can continue to be used safely, there is no justification for not permitting continuation for a full 15 years.
- Item 15 inserts a new division for continuation applications. CropLife suggests that several improvements could be made to this process to ensure that it is not simply a bureaucratic exercise and achieves its objectives efficiently. Again, the overall impact on registrants will be determined by the way that this reform is implemented and administered, which will be informed by the risk management framework that is yet to be released. However, CropLife does make the following comments:
    - The proposed new Section 51B requires registrants and approval holders, when making a continuation application, to provide the APVMA with the information that it requires. Greater clarity about the information that the APVMA requires will be necessary, otherwise applicants may simply provide the same information as the original application package on the assumption that that would be sufficient. To avoid continuation applications merely becoming a process that duplicates the original application, **CROPLIFE RECOMMENDS** that the APVMA specifically identify the type of information that will be required to provide an acceptable application to the APVMA.
    - The proposed Section 51B also requires registrants and approval holders, when making a continuation application to provide the APVMA with both information about the relevant particulars and any conditions of the approval or registration. This may cause problems for the APVMA and secondary registrants where conditions of registration are simply copied from an original registrant. Further, it is highly likely that in many circumstances, an original registrant would be unwilling to provide information on conditions of registration where it provides a commercial advantage. In these circumstances, it is unclear how providing relevant particulars or conditions of approval and registration could facilitate any improvement in the risk assessment conducted by the APVMA. If it is the intention of these proposals to confirm that the formulation of products currently sold on the Australian market reflect that originally approved by the APVMA, then this could be achieved by simply asking registrants to confirm that their products remain compliant with the standards approved when the product was registered, and that current particulars remain accurate and relevant.

- CropLife notes that the Regulation Impact Statement suggests a process that appears to be substantially different to that outlined at Item 15. The Statement outlines potential consideration of overseas decisions to ban or list under environmental treaties. While CropLife notes that these requirements do not appear in the exposure draft legislation, CropLife would not support the inappropriate and unfair use of overseas decisions and treaties in the decision making process. This would include references in both subordinate regulations and the proposed risk framework.

- Item 15 requires that continuation applications be submitted between three and six months prior to expiry of the approval or registration. CropLife suggests that continuation applications should be able to be made up until the day before the relevant approval or registration expires. As there are already provisions for the approval to continue until the outcome of the continuation application is known, there is no genuine reason to restrict applications made less than three months prior to expiry.

- Item 15 also provides that, "The APVMA must notify an approved person no later than 14 days before the latest date on which a continuation application is required". A 14 day notice period is unlikely to be a sufficient timeframe for registrants to prepare and submit a continuation application – especially if it relates to an active constituent approval, or where a registrant does not have access to all the information necessary to make a continuation application and may need to negotiate with third parties. CropLife has previously discussed a nine month notification period and would recommend extending the notification timeframe to nine months.

- As discussed earlier, products with multiple active constituents should not be subjected to a greater compliance burden. **CROPLIFE RECOMMENDS** that products with multiple actives should only be subject to a continuation application when the first of the included actives is set for reconsideration by the APVMA. When other actives in that product are set for reconsideration, the product would not be required to duplicate its continuation application process.

- CropLife supports the proposed approach in the proposed new Section 51D to allow registrations and approvals to continue until such time as a decision has been made. This will be important to ensure certainty for registrants while continuation applications are assessed.

- The continuation application process potentially serves as a transparent and accountable system for identifying those active constituents that are in need of review. However, it would be undesirable if the only outcome of continuation applications was that the current list of chemicals scheduled for review was expanded, without providing for the supporting mechanisms and structures necessary to support the timely conclusion of reviews.

  CropLife understands that the package of reforms suggests that fixed timelines for completion of a chemical review would be specified. Currently, there is some uncertainty regarding how timelines for chemical reviews would be established. Given the uncertainty regarding the directions that reviews may take, CropLife would welcome the opportunity for further consultation on review timeframes. Timeframes must facilitate active participation by registrants and must not set artificial deadlines that only work to remove products from the market without adequate opportunity to provide supporting material.

- CropLife notes that the exposure draft legislation contains several opportunities for registrants to comment on decisions made by the APVMA in relation to a continuation application (such as in the proposed S51G(2). CropLife supports this approach as an essential mechanism and encourages open communication between registrants, approval holders and the APVMA at all stages of the application process. CropLife does note that in some circumstances, the 28 days allowed for continuation applicants to comment would not be likely to be sufficient, especially when the issues being considered by the APVMA are complex. While additional time can be requested, it is expected that this will only occur in circumstances where the extension can be accommodated within the total time required for a decision on the continuation application to be made by the APVMA.

Recommendation 13:
The proposal for a continuation application scheme should be removed from the package of reforms.

Recommendation 14:
A continuation application scheme should not commence until a risk framework is in place that provides certainty around how continuation applications will be assessed.

Recommendation 15:
Approvals and registrations should be prioritised for reconsideration according to the date of first approval or registration rather than by using any hazard based criteria.

Recommendation 16:
Continuation applications should be able to be made up until the day before a registration or approval expires.

Recommendation 17:
The APVMA should be required to provide advice to approval holders or registrants about the need to make continuation applications at least three months before expiry.

Recommendation 18:
Additional consideration should be given about how generic products that may not have access to conditions of approval or registration should be handled by a continuation process.

Schedule 3 – Streamlining processes for giving and receiving information

CropLife supports those reforms that are designed to improve the efficiency of the APVMA. Many of these reforms are long overdue and merely bring the APVMA up to a modern standard for a regulatory agency. For example, enabling the APVMA to accept electronic applications for many application categories should facilitate faster consideration and decision. This will also reduce costs for applicants. Electronic application systems have the potential to ensure that incomplete applications are automatically not accepted by the APVMA until shortcomings are addressed. Properly implemented, electronic applications can free the APVMA to focus on complete, high quality applications rather than dedicate resources to incomplete applications.

CropLife welcomes any reforms that can be demonstrated to deliver efficiency benefits to the regulatory system for agricultural chemicals. Improving the APVMA's efficiency will permit it to better meet its statutory obligations to deliver regulatory decisions within the required time frame. However, care must be taken to ensure that the reforms proposed genuinely result in greater efficiency across the regulatory system as a whole. It would not be acceptable to CropLife or its members if the APVMA was only able to improve its administrative efficiency by increasing the regulatory burden placed upon applicants and registrants. Efficiency requires improvements across the whole registration process - merely shifting responsibility and functions on to applicants is not acceptable.

CropLife is concerned about the lack of any cost and benefit analysis for the reforms contained in the exposure draft legislation. As the reforms have potentially both significant risks and benefits to applicants, registrants and approval holders, it is critical to be assured that the reforms will deliver a net benefit to industry. Without this assurance, CropLife would be concerned that the reforms will not deliver the efficiencies expected. Several of the reforms proposed, by implementing rigid approaches to accepting new data or changing application categories, may in fact be decreasing the overall efficiency of the regulatory system.

For example, if the proposals operate in such a way that applications are refused due to minor technicalities, then the applicant is likely to resubmit that application. This results in the APVMA having to process the application several times and requires the applicant to pay multiple application fees. As application fees do not cover the full cost of conducting a risk assessment for the product, this process would not be efficient for either the applicant or the APVMA. If the APVMA wishes to improve the quality of applications to minimise workload at screening, then much clearer guidelines need to be provided to registrants than those currently in the APVMA's Manual of Requirements and Guidelines. CropLife expects that this should be provided through a comprehensive risk framework, and these must be in place before measures to streamline processes commence.

In particular, for more complex applications seeking approval for new active constituent and associated products, there is greater uncertainty about the type of information that may be required to establish a products' safety. Currently, there is a certain degree of interaction between applicants and the APVMA to clarify areas of uncertainty or to address potential questions over the course of an evaluation.

While it is intended that the risk framework will assist in ensuring that applications meet APVMA requirements, CropLife is sceptical that it will be able to anticipate the requirements that may be required for entirely new classes of chemistry that may be developed.

An ideal system must incorporate some flexibility to enable the APVMA to properly assess applications that can be rectified, while precluding assessment of those applications that are so deficient that they present an unacceptable drain on APVMA resources.

Without an appropriate level of flexibility to facilitate limited and effective interaction between applicants and the regulator, the proposed elapsed time framework and the shut-the-gate provisions will, as the Regulation Impact Statement identifies, increase the number of applications that are withdrawn. As the consequences of rejecting an application for a new active constituent can have major reputational and regulatory implications in other key markets around the world, global companies may seek to minimise this risk by delaying or avoiding Australian introduction. As a consequence, CropLife remains concerned that the actual outcome of these provisions will not achieve the stated aim of encouraging companies to 'develop and introduce modern and safer chemicals into the Australian market'.

While CropLife does note that proposed changes to section 159 will allow some limited capacity for applicants to address shortcomings identified during evaluation, its practical effect is still inflexible and may hinder the efficient processing of applications.

While CropLife supports the measures that intend to prevent applicants from gaming the system by making applications that are sub-standard or deficient, some targeted, efficient reforms could ensure that an appropriate level of flexibility is permitted that facilitates genuine discussion between applicants and the regulator to address scientific uncertainty in an application.

CropLife considers that it is unfair for an applicant that has compiled a complex application in good faith, and complied with all requirements and guidelines should face the major negative consequences of having their application rejected, despite the applicant being willing to commit to a study plan to generate the information required to satisfy the APVMA that an active constituent or product can be approved or registered.

CROPLIFE RECOMMENDS that the Government consider whether amendments to the draft exposure legislation should be made that:

- Enable risk assessments made by APVMA external agency partners to be provided to registrants as soon as they are available to allow prompt clarification by applicants;
- That if the APVMA identifies a deficiency that may threaten the success of the application, the APVMA must always identify this in their s159 letter, providing the applicant with a reasonable opportunity to address the deficiency with additional data or argument; and
- Allows applicants, when faced with the need to generate additional data (which could not have reasonably been foreseen at the time of lodging their application) with the opportunity to initiate an extension to the assessment period. This would allow an applicant to effectively freeze the application for the period required to generate additional data, and then to pay a subsequent fee for completion of the particular modular assessment requiring the additional data.

These issues again highlight the need for a comprehensive risk framework to be implemented prior to commencement of these arrangements. The risk framework must provide greater certainty to applicants about how their application will be assessed to facilitate better quality and more complete applications that can be rapidly assessed by the APVMA, and minimise the scope for uncertainty in APVMA requirements.

CropLife notes that one of the key reforms proposed is the expanded adoption of electronic applications and communication by the APVMA. This reform is well overdue and supported by CropLife. The introduction of greater electronic communications will result in enhanced communication between the APVMA and avoid some of the excessively formal approaches to communication previously employed.

CropLife makes the following observations regarding specific items in the exposure draft of the legislation.

- Items 12 and 13 of Schedule 3 are examples where a cost and benefit analysis would be useful. While CropLife acknowledges that there may be efficiency benefits associated with the requirements for new legislation, this approach would also limit APVMA flexibility. CropLife can only support this proposal if it can be demonstrated that it will result in a net improvement in the APVMA's efficiency.

- Removing requirements for applicants to rectify applications increases the need for less ambiguity in the APVMA's regulations and guidelines. CropLife expects this to be provided through the comprehensive risk framework, but again this must be in place before provisions removing rectification commence.

- Items 14 to 19 remove the opportunity for applicants to rectify applications and for the APVMA to defer consideration of applications. This reform can only be accepted where it can be demonstrated that they will provide a net efficiency gain. Again, prior implementation of a comprehensive risk framework will be essential to give applicants the information that they need to develop and submit high quality applications.

- Items 22 and 23 specify the information that the APVMA is required to consider when conducting chemical reviews. The intention is to facilitate the APVMA's capacity to complete chemical reviews in a timely manner and to encourage approval holders and registrants to submit any data at an early stage. However, an unintended consequence of this approach may be that the APVMA is required to approve an active constituent or product when it has new information that raises additional concerns about the risks associated with its use. These provisions preclude the APVMA from considering that information. CropLife has long suggested that a superior approach is to provide better arrangements to encourage registrants and approval holders to collaborate to generate new data. The APVMA must always be allowed to consider all the data available to it to ensure that its assessment of chemicals is both accurate and meets contemporary standards. Allowing all information to be assessed will help preclude the possibility that the APVMA would approve an active constituent and then be required to immediately again place it under review. A process where this occurred would be neither efficient nor effective for either industry or the regulator.

- Items 22 and 23 also note that fixed timeframes will be imposed for completion of chemical reviews. Regulations setting the fixed time for the review must be long enough to allow time for approval holders and registrants to negotiate and establish review task forces, generate necessary data (which may mean multiple growing seasons' field trials), as well as allowing the APVMA sufficient time to assess any data generated. CropLife envisages that at least several years will be necessary to for a complex chemical review involving multiple partners to be completed.

- Item 32 requires the APVMA to decide applications within the total elapsed time established by the regulations. CropLife notes that at this stage the proposed timeframes are not available as supporting regulations have yet to be drafted, however, the timeframes that are ultimately specified must reflect the time that will be required to assess the most complex applications. Implementation of fixed timeframes, as noted elsewhere in this submission, is predicated on improving the quality of applications made to the APVMA. Improving the quality of applications is in turn reliant upon a published comprehensive risk framework.

- CropLife would not support total elapsed timeframes for determining applications if it meant that the APVMA was required to refuse an application in circumstances where it was unable to complete an application within the required time frame. This would simply lead to another application being made and increase the administrative burden on the APVMA and the regulatory burden on the applicant.

- Item 45 specifies when the amendments in Schedule 3 apply. As many of the proposed legislative reforms are reliant on the existence of a comprehensive risk framework, this item must be reviewed to ensure that it allows sufficient time for the risk framework to be developed.

CropLife notes that it is the Government's intention to provide pre-application assistance for applicants as a method of improving the quality of applications the APVMA receives. CropLife can only support pre-application assistance provisions in circumstances where it does not result in applicants seeking to use the APVMA as a *de facto* consultant.

CROPLIFE RECOMMENDS that applicants that seek to take advantage of pre-application assistance should pay the true cost of providing that service to the APVMA. Applicants should not receive a reduction in application fee after they have used this service. Unless these approaches to pre-application assistance are adopted, all applicants are likely to use this service, increasing the drain on the APVMA's resources without any corresponding increase in income.

Recommendation 19:
A strictly limited opportunity to rectify applications in some circumstances after the application has been accepted by the APVMA should be permitted to provide some flexibility.

Recommendation 20:
Measures to restrict flexibility of the current system should only occur after comprehensive risk frameworks have been developed, providing greater clarity and certainty for applicants.

Schedule 4 - Enforcement

CropLife supports the expanded toolkit for the APVMA that will be provided as a consequence of the exposure draft legislation. Ensuring that the APVMA has a comprehensive suite of graduated tools that enable proportionate responses to compliance issues will remain increasingly important. It will ensure that the APVMA is not excessively focussed on technical compliance by registrants, but focused across the entire industry, including those seeking to avoid regulatory controls.

Importantly, the APVMA must seek to deploy its monitoring, compliance and enforcement toolkit in ways that focus its resources on those individuals and organisations that present the greatest risk. As a result, CropLife suggests that a particular focus should be put on new importers and manufacturers to ensure that their manufacture and import of active constituents and product reflect the approvals and registrations obtained.

CropLife supports reforms that are designed to give the APVMA an appropriate range of tools that enable it to effectively administer the Agricultural and Veterinary Chemicals Code and to also identify and respond to incidents of non-compliance. Agricultural chemicals, by their nature can have significant negative consequences if their quality is not controlled and their use not strictly managed. Loss of access to export markets can occur from residue detections in commodities. Due to these significant consequences (and other potential environmental and health effects), it is appropriate for significant penalties to be available.

Controlling and monitoring Australia's agricultural chemical portfolio is an administratively complex task for both the regulator and registrants. From time to time, registrants of products and approval holders may inadvertently breach minor administrative controls. For example, due to the global nature of the agricultural chemicals industry, active constituents for products can come from any one of a number of production facilities around the world. Should a registrant change supplier for an active source without notifying the APVMA, then the registrant could be in breach of their obligations under the Agricultural and Veterinary Chemicals Code. Provided that the breach has no effect on the health or safety of the products being supplied to Australian users, CropLife would oppose excessive enforcement actions from being imposed. It is critical that any penalties imposed must reflect the magnitude of the offence that has occurred, and the compliance effort of the APVMA must reflect the risk of harm that results from any breach.

CropLife welcomes the focus on greater compliance powers by the APVMA, but these should also be supported by greater compliance activity on the part of the APVMA. This should be focussed on those potential breaches that result in the greatest increase in risk to users, consumers, the environment and trade.

CropLife is keen to ensure that the APVMA does not limit itself to enforcing administrative and technical breaches of registrants while ignoring potentially much more significant breaches by individuals and companies, such as the import and distribution of unregistered and counterfeit chemical products. The APVMA must not become the regulator solely for the legitimate industry and must ensure that it has the regulatory setting in place to deter, detect and respond to illegitimate activities that present the greatest risk to users, consumers and the environment.

CropLife makes the following observations in relation to specific provisions of this schedule:

- CropLife notes that many offences have been amended to increase the penalty for breaches from 30 penalty units to 50 penalty units. However, the amendments at Items 121 to 131 of Schedule 4 increase the penalty to 60 penalty units. For the sake of consistency, CropLife suggests that these offences should also be set at 50 penalty units. CropLife would welcome discussion with the Government on the reasons why penalties in Sections 88 and 89 of the Agricultural and Veterinary Chemicals Code Act justify greater penalties.
- CropLife supports and welcomes the introduction of the new offence at Item 135 relating to counterfeit products and active constituents. Counterfeit products are a growing problem globally and the APVMA must have a comprehensive toolkit to facilitate appropriate responses to incidences where counterfeit products have been manufactured or imported.

- CropLife supports implementation of new tools for the APVMA to respond to breaches of permit conditions. CropLife notes that Item 151 of Schedule 4 provides that the APVMA may now prosecute persons that breach permit conditions. Persons that breach conditions associated with permits can subject users, consumers and the environment to unacceptable risks in the same way that registrants and approval holders can. CropLife therefore considers that it is appropriate that permit holders are subject to similar penalties in circumstances where breaches of permit conditions occur.

CropLife also supports the introduction of civil penalties for many of the offences contained within the Agricultural and Veterinary Chemicals Code. Allowing civil penalties can facilitate a more rapid, effective and timely enforcement of breaches of the Code. Civil penalties are an important part of developing a graduated approach to compliance and enforcement by the APVMA.

Schedule 5 – Data Protection

CropLife supports and welcomes proposals for improved data protection, which will improve the incentive for innovators to bring newer, safer and softer chemicals to Australia. However, an important addition to data protection provisions relates to the extension of protection afforded to data submitted as part of a chemical review process.

In contrast, CropLife remains disappointed that many of the additional measures that are necessary to encourage registrants to participate in chemical review task forces are absent. Without these additional requirements (which include measures that require registrants of products with a chemical under review to indicate their intention to participate or have their registrations cancelled) there remain significant incentives for product registrants to free-ride on the data generation of the approval/registration holder. This arrangement works against the objective of facilitating more rapid chemical review processes.

CropLife remains concerned that data protection for new agricultural chemistry remains insufficient. **CROPLIFE RECOMMENDS** that data protection for new chemical products be extended to ten years for new active constituents. This will bring Australian data protection provisions into line with several key trading partners and encourage investment and innovation in new products for Australian farmers.

CropLife welcomes the improvements to data protection contained within the exposure draft legislation. Data protection is a key incentive for innovative companies to develop newer, better targeted and more effective crop protection products for farmers and other users. Without adequate data protection provisions, it is unlikely that any companies will develop specific products that reflect Australian farming systems and environments. Instead, farmers may be forced to rely on a diminishing set of older, generic technologies.

While the reforms contained in the exposure draft legislation are welcomed, they are insufficient to maintain competitiveness with other economies and markets. Greater investment in Australian specific crop protection products could be achieved with better incentive for innovation.

For example, the current regime of providing eight years data protection for new products with the potential to access another three once minor uses have been added, has not been effective in providing sufficient incentive for registrants to add additional uses for new products onto labels.

CropLife suggests that in addition to the proposals included in the exposure draft legislation, the following reforms should be made:

- CropLife proposes extending data protection for new products to ten years (increased from the current eight) to bring data protection provisions into line with other competitive economies such as the United States. This will provide a genuine incentive for companies to develop new products tailored to Australian conditions.

- Measures should also be put in place to equitably treat innovative and generic producers of chemical products. Innovative registrants that develop products and access patent protection lose a significant proportion of that protection due to the time taken to progress through the regulatory assessment process. This loss is compounded at the end of the period of protection where competitive generic products can be assessed while patent protection remains, but not be registered or sold until such time as the patent protection has expired. While 'spring boarding' new products in this way may have perceived benefits (as it can more quickly reduce the cost of products to users) innovative companies must be treated equitably. CropLife would suggest that amendments be made to the Agvet Code to either prevent assessment of a product from occurring until patent protection has expired, or to provide a minimum effective patent period as occurs for therapeutic goods.

CropLife does note with concern one consequence the current exposure draft legislation with respect to data protection. If an applicant makes an application that satisfies the APVMA on all elements except one, the APVMA will reject the application. If the application then submits a modular application that addresses that one concern, and the APVMA then approves the application, data protection will only be given for that one element that the APVMA relied upon in granting the application. Data protection will not be able to be given for the remaining elements that the APVMA considered satisfactory, but were not used as part of the second, modular, application. This represents an unacceptable loss of proprietary information, and should be remedied by the Government before introduction of the legislation.

CropLife welcomes measures to enable data subjected under permit to be able to be protected when relied upon by the APVMA in a subsequent application. This will provide greater incentive for registrants and other developers of data (such as grower groups) to collaborate on getting new uses on to labels.

As mentioned previously, data protection associated with Category C data (data submitted under a chemical review) remains inadequate. CropLife has provided information to the Government on several occasions in respect of the reforms necessary to encourage registrants to provide data to a chemical review process. While there are some improvements that have been included in the exposure draft legislation, a comprehensive package of data protection reforms is required to encourage registrants to actively engage in the chemical review process. The comprehensive package of reforms required is at ***Attachment A: Policies to facilitate data sharing and compensation negotiations.***

Schedule 6 – Arrangements for Collecting Levy

CropLife supports the most effective and efficient collection of the sales levy. CropLife has no view about the ideal agency that should be responsible for collection. If it can be demonstrated that alternative collection arrangements will be more efficient than those currently in place, then CropLife would support this reform.

CropLife looks forward to working with the Government to investigate the efficiency of reforms for the collection of levy.

Conclusion

In considering the package of reforms contained within the *Better Regulation* exposure draft legislation, CropLife has sought to confirm, but is unable to establish that there is a net benefit to registrants of agricultural chemical products nor the broader community . CropLife remains concerned that the efficiency benefits expected will not accrue. Instead, CropLife considers that there is a real and genuine risk that these efficiency reforms will actually increase the current inefficiency of the system. Further, CropLife does not accept that there is likely to be any demonstrable improvement in workplace health and safety, consumer protection or environmental protection as a result of the continuation application process.

The Cost Recovery Discussion paper prepared by the APVMA indicates that implementation of these reforms will increase the cost to agricultural chemical producers by as much as $8 million each year[5]. In turn, this increase in cost recovery from the industry may have a detrimental effect on the availability of accessible chemicals for Australian production systems.

The current proposals have ignored key areas of potential reform and introduced new processes that are not linked to problems that have been identified by several independent reports. The limited (if any) benefits associated with the efficiency reforms do not outweigh the significant expense and additional inefficiency that will result from implementation of these reforms.

For these reasons, CropLife encourages the Government to re-examine the package of reforms to include potential areas where genuine efficiency reforms could be achieved. CropLife also encourages the Government to reconsider reforms around continuation applications to ensure that some improvement in human health or environmental benefit can be demonstrated that outweighs the additional costs from increased regulation and bureaucracy.

[5] Cost Recovery Discussion Paper Covering the Period 1 July 2012 to 30 June 2015, APVMA, p47.

Attachment A

POLICIES TO FACILITATE DATA SHARING AND COMPENSATION NEGOTIATIONS

1. Data protection commences from the time of the interim (if there is one) and the final reconsideration decision.
2. All data relied upon for the reconsideration decision is eligible for data protection and any data not relied upon may be resubmitted in support of a future application for registration/approval of data call, and be eligible for data protection. ('Not relied upon data' is new policy).
3. The data provided under Class C must be placed in the Protected Information Register in the same manner as that currently utilised for Classes A and B (ie. no additional detail or disclosure).
4. Registrants must indicate to the APVMA their willingness to provide the required data either separately or jointly with other registrants at the time of the initial data call. If not willing to provide the required data, their registrations/approvals are to be cancelled within a prescribed time. (Policy change)
5. During or after the completion of the reconsideration, the APVMA can only register new products and approve new sources of active constituent after notification by the data owner(s) and/or arbitrator that a compensation agreement has been reached. Registrants who own existing data must offer to share that data under a compensation arrangement with other registrants and form a taskforce prior to submission of the data. (Prior to submission of existing data is a policy change).
6. Registrants who elect not to join a taskforce holding existing data and instead provide their own data must demonstrate to the APVMA that the data is being generated according to prescribed timeframes.
7. Registrants who default on their agreement to provide data (or join a taskforce) must be liable for compensation to other registrants and lose their registrations.
8. The APVMA must be given timeframes and enforcement powers for the critical action points relating to data call-in, provision of data and actions against defaulters that occur during the review process. (The 2003 Policy Paper contains a number of critical timeframes that will need to be reconsidered and further defined as the policy changes. These timeframes will need to be considered for their objectives and practical implications at the draft legislation consultation stage.)
9. Compensation can be voluntarily negotiated either with or without the services of a compensation facilitator. This facilitator is to assist parties with compensation negotiations so as to avoid, where possible, arbitration. The APVMA should not have any direct involvement in the process except to provide information to the facilitator/arbitrator on studies conducted. The services of the facilitator are to be paid for by the parties on an equal share basis. (New policy to replace the arbitration authority and its function - facilitator to act like a mediator but have (develop) expertise in pesticide compensation to guide the parties on a practical outcome and the consequences of not achieving a voluntary outcome).
10. When a voluntary negotiation breaks down the parties must participate in arbitration using the Institute of Arbitrators & Mediators Australia (IAMA). (New policy as alternative to the arbitration authority).
11. Arbitration must commence within 90 days of receipt of the APVMA's request for data if voluntary negotiated arrangements have not been reached sooner. (New policy – currently no specified timeframe). Critical milestones for the arbitration process to be legislated as per DAFF's May 2003 Policy Paper.)
12. The decision of an arbitrator is binding and not appealable, except as provided for in law.
13. The legislation will not provide a compensation formula. The quantum of compensation will be negotiated by the parties. (Policy change)
14. The public Arbitrations Register is not supported (Policy change). This information should be recorded by IAMA and available for use only by other arbitrators.
15. Legislate for active constituent manufacturers to only be able to obtain approval to supply in Australia if they have a legal presence in Australia. Consequently, allow registrants an exemption from supplying data on the basis that they purchase active constituent from an approved source.