CropLife AUSTRALIA

SUBMISSION IN RESPONSE TO

POLICY DISCUSSION PAPER

BETTER REGULATION OF AGRICULTURAL AND VETERINARY CHEMICALS

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INTRODUCTION/EXECUTIVE SUMMARY

CropLife Australia (CropLife) is the peak body representing the plant science industry in Australia. CropLife welcomes the opportunity to make this submission in response to the Policy Discussion Paper *Better Regulation of Agricultural and Veterinary Chemicals* and to provide the views of CropLife members with respect to the proposals contained within the paper.

Australian farmers are among the most innovative and efficient in the world. Farmers need to continue to innovate to meet the combined challenges of climate change, food security and to recover from the global financial instability of the previous two years.

CropLife believes that any regulation of agricultural chemicals must be both effective and efficient.

Regulation must first be effective. It must achieve the outcomes and objectives that it is designed to implement. For agricultural chemicals, this means that regulation must facilitate farmer access to useful pest, weed and disease control options while protecting workers, consumers, the environment and trade markets from unacceptable risks associated with agricultural chemicals.

Secondly, regulation must also be efficient. The objectives of protecting health, environment and trade should be achieved in a manner that minimises the impact on users and businesses. Efficient regulation of agricultural chemicals will encourage innovation, providing industry with the incentive to research, develop and register newer, safer and softer chemicals that are better targeted.

CropLife has long sought efficiency improvements in the regulation of agricultural chemicals in Australia. To that end, we welcome the Government's focus on providing reforms that seek to improve the efficiency and effectiveness of agricultural chemical regulation. CropLife notes that the intention is to cut unnecessary red tape and encourage the development of modern, cleaner and safer chemicals. However, CropLife is concerned that, if implemented poorly, some of the proposed reforms could have significant destructive effects on Australian agriculture. We are particularly concerned that despite this stated objective, many proposals will:

- increase costs for registrants and farmers;
- result in safe and effective chemicals being withdrawn from the market; and
- potentially result in poor user, consumer and environmental outcomes.

Our response to the Policy Discussion Paper *Better Regulation of Agricultural and Veterinary Chemicals* highlights our areas of greatest concern It seeks to outline where CropLife agrees with proposals, those issues where CropLife could potentially support a proposal provided that certain adjustments, guarantees or conditions were imposed, and those proposals that would benefit from a closer assessment of costs and benefits to ensure implementation delivers actual benefits that outweigh their costs to industry, farmers, and the Australian community.

CropLife is looking forward to working with the Government to ensure that the reforms proposed can be implemented in a way that improves both the protection of human health, the environment and trade, as well as improving the productivity of Australian agriculture by encouraging innovation.

While certain recommendations contained in the Policy Discussion Paper apply to both agricultural as well as veterinary chemicals, all comments in this submission should be read as only applying to the proposals as they apply to agricultural chemicals.

PROPOSED COMMONWEALTH REFORMS TO LEGISLATION AND REGULATIONS

General Comments

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

CropLife, governments and the Australian community would not, and should not, support regulation that would diminish the level of protection afforded to users, consumers and the environment. However, significant progress could be achieved by minimising and avoiding the impact that duplications, inconsistencies and inefficiencies have on the industry.

While CropLife welcomes the Government's focus on improving agricultural chemical regulation, many proposals appear to cut against the stated objective to reduce the regulatory burden on industry. This is particularly concerning when there is no clear health or environmental benefit that is likely to accrue from these reforms. CropLife would be disappointed if efforts by governments and industry to improve the efficiency of chemical regulation in Australia were undermined by poorly considered reforms that increase agricultural chemical regulation without benefit. CropLife has participated in a number of government reform activities over several years and is still waiting for much of the benefit from these activities to be realised. These have recently included *Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business* that identified chemicals and plastics regulation as a key regulatory hot spot and a priority for reform. In response, the Productivity Commission's 2008 report on *Chemicals and Plastics Regulation* also made a number of recommendations (yet to be implemented) designed to reduce burdens on business.

One of these reforms is currently being developed by the Product Safety and Integrity Committee (PSIC) to develop a nationally harmonised system for the regulation of agricultural chemicals. CropLife's responses to this discussion paper must be considered in the context of this parallel process. Many of the proposals contained within this Discussion Paper will be impacted by the content of the national harmonisation consultation regulation impact statement (Consultation RIS) that CropLife expects to be released in the near future. CropLife reserves the right to revisit and revise the positions expressed in this paper once the recommendations contained within the Consultation RIS are available.

Broadly, CropLife notes that the discussion paper contains limited discussion of the resources (both financial and technical) that would be required to implement the various proposals. The Discussion Paper also fails to identify from where these additional resources would be sourced. Many of the proposals impose additional functions or obligations on the APVMA, but there is little discussion about the impact that these additional tasks and functions would have on the capacity of the APVMA to provide timely risk assessments and registrations. CropLife is already critical that the APVMA is tasked with too many 'non-core' functions and believes that many improvements in timeliness, efficiency and registration performance could be achieved if the APVMA was stripped of these functions and permitted to focus on its core business of providing high quality risk assessments and timely registrations. CropLife would be concerned that giving additional functions to the APVMA would further diminish the Authority's performance with respect to providing on-time risk assessments and registrations.

CropLife would have welcomed greater consideration of how additional tasks and functions should be funded. CropLife notes that the APVMA has already come under significant scrutiny and criticism because it is currently almost exclusively funded by fees and levies recovered from industry. While CropLife does not agree that the APVMA has been 'captured' by registrants, CropLife does consider that it is important for the Authority to be both independent, and seen to be independent. Progress towards this goal could be achieved by the Federal Government providing additional resources to support the non-core functions of the APVMA.

Ultimately, CropLife's support for many of the proposals outlined will be contingent upon a clear demonstration that there are benefits to industry that outweigh their cost. To that end, CropLife will be seeking a rigorous cost/benefit analysis of each of the reforms prior to their implementation.

1. Implementing complete risk frameworks for agvet chemicals assessment and review

> The APVMA, in consultation with its regulatory partners including the Office of Chemical Safety and Environmental Health (OCSEH) and the Department of Sustainability, Environment, Water, Population and Communities (SEWPaC), would develop an overarching risk framework for agvet chemicals.

CropLife supports this recommendation, but notes that the determination of what level of risk should be considered acceptable is a policy decision that should be made by the Federal Government Department of Agriculture, Fisheries and Forestry (DAFF), rather than a cost recovered agency that is responsible for providing agricultural chemical risk assessments and registrations.

The development of an acceptable cross portfolio risk framework will require significant commitment, resources and time from DAFF, the APVMA and its regulatory partners. While CropLife welcomes the proposal to develop the framework, CropLife does not believe this activity should be funded exclusively by resources recovered from industry. To do so would result in an unacceptable cost-shifting of core government functions onto industry.

Further, taking APVMA staff away from their core business of providing high quality registrations and risk assessments of agricultural products will impact on the capacity of the agency to provide timely, high quality risk assessments and registrations. The size and potential complexity of this task should not be underestimated. The risk framework surrounding agricultural chemicals is detailed and comprehensive. Depending on the terms of reference for developing the risk framework, the activity could potentially involve many federal, state and territory regulators. Rather than improving the efficiency of the regulator, development of the comprehensive risk framework could result in deterioration in the services provided by the APVMA, to the detriment of CropLife members.

CropLife recommends that primary responsibility for producing the risk framework be given to DAFF with significant support and input from the APVMA, its regulatory partners and registrants. The Department would then be responsible for conducting negotiations and liaising with all agencies with an interest in the overarching risk framework for agricultural chemicals. Alternatively, in recognition that the risk framework surrounding agricultural chemicals currently involves significant responsibility by state and territory governments (especially surrounding the use of agricultural chemicals) CropLife recommends that DAFF could use the existing Primary Industries Ministerial Council to take into account those elements of the risk management framework that relate to the use, rather than the registration and risk assessment, of agricultural chemicals.

CropLife notes that should this proposal be accepted, the resulting risk framework would be likely to better reflect both federal and state responsibilities for agricultural chemicals without shifting the costs of this activity on to industry. Clearly, the APVMA will have an important role in informing the development of the overarching risk framework, as it will primarily be responsible for applying it to risk management decisions regarding agricultural chemicals. CropLife would support its involvement in the process, but not proposals to make it responsible for delivering the overarching risk framework.

The APVMA and its regulatory partners would be required to develop and publish all relevant risk manuals, standards and methodologies which guide decisions about the level of risk of a particular product or active ingredient.

CropLife supports the open and public communication and publication of all manuals, guidelines and procedures by relevant agencies. Adding to the existing environment guide would be a welcome and useful tool, not only to communicate the risk framework to interested members of the public but to also ensure there is better alignment between the level of assessment with the level of risk associated with a particular product.

However, CropLife does note that the existing environmental component was funded and prepared by the Environment Protection and Heritage Council under the auspices of the National Framework for Chemicals Environmental Management (NChEM). It required only minimal technical resources to be drawn from the APVMA. Further, it was developed to provide general community guidance regarding environmental risk management rather than to prescribe the processes and procedures followed by the APVMA and SEWPaC. This different focus should be recognised.

CropLife would support a similar approach to be applied with the remaining components with Government revenue used to develop additional components, rather than financial and technical resources being drawn from the APVMA.

The APVMA does not have an exclusive responsibility to explain its policies and procedures to the public. Federal, state and territory governments all share a responsibility to assure the community that they have appropriate procedures, guidelines and safeguards in place to protect the community and environment from the adverse effects of agricultural chemicals. The APVMA can, and does defend its processes, but federal, state and territory governments should also defend the APVMA's function as an independent assessor of agricultural chemical risk. It is, after all, the government that determines the acceptable level of risk, and the processes that the APVMA must go through when considering whether to register an agricultural chemical.

2. Improve the quality and efficiency of agvet chemical assessment and registration processes

In addition to its obligation to the community to explain its processes to the public, the APVMA would offer an upfront (one-off) pre-registration assistance session to each prospective applicant.

CropLife understands that the objective of this proposal is to help applicants determine the information and quality requirements for their application before submission to the APVMA. CropLife welcomes the reform as a mechanism that has the potential to facilitate the rapid assessment of applications by identifying application deficiencies early in the application process. However, CropLife does not support the proposal that this process be offered to all applicants on an individual basis and form part of the standard fee for a product application. CropLife is concerned that to do so would disadvantage those highly professional and capable registrants that have no need for this service. The result would be an unacceptable cross subsidisation of applicants requiring assistance by those that do not.

It would be preferable for this service to be offered on a cost recovery basis. Given that an objective of these reforms is to improve the efficiency of agricultural chemical regulation, adding additional functions (and associated cost) to the standard APVMA risk assessment is not necessary. For many applicants this would merely result in additional cost without any extra benefit being provided.

CropLife does note that a pre-application consultation between an applicant and the APVMA would have the potential to assist inexperienced applicants that are not very familiar with the guidelines for making an application to the APVMA. While support for inexperienced applicants is welcome, and supported, two issues need to be addressed to ensure that this process does not adversely affect existing application processing.

Firstly, the APVMA has limited technical resources. CropLife would not support this proposal if it resulted in significant technical resources being reallocated to meet demand for pre- application consultations. Ultimately, the APVMA should not be a de-facto consultant for applicants seeking advice and coaching to get products registered.

Secondly, if the Government wishes to assist small companies, businesses or individuals to develop and register agricultural chemical products, this assistance should most properly be provided through a program administered by the Federal Department of Innovation, Industry, Science and Research. Small business assistance should not be provided by a cost recovered regulator where it will impact upon existing risk assessment activities.

CropLife suggests that the Government should consider the option of providing regular training to all registrants as an alternative to one-on-one pre- application consultation sessions. This would have the advantage of significantly reducing the cost to the APVMA of providing these sessions (and thus registrants) and also avoid any equity, accountability or transparency considerations that would need to be taken into consideration due to a pre-application consultation.

Alternatively, should the Government be committed to introducing one-on-one pre-application assistance, costs could be minimised by limiting availability to those application categories that are more complex. Simple applications such as a repack or minor label changes should not have access to pre-application assistance. CropLife would be willing to work with DAFF to determine the appropriate scope of availability.

The option to access further pre-registration assistance would be available, on a cost recovery basis, for those applicants who choose to seek further advice or clarification on a particular application.

CropLife notes that imposing cost recovery for these services would remove concerns that the processes result in an unacceptable subsidisation of competitor's applications. However, it may still result in technical resources being drawn from the assessment and registration of products to this sort of industry assistance activity.

An analysis of the current performance of the APVMA's statistics shows that over 20% of all applications are currently not being finalised within statutory time limits. A further dilution of the technical resources available to the APVMA, without mitigating actions would be likely to increase the rate at which products are not finalised within required timeframes.

Increases in applications not meeting legislative deadlines for finalisation would not be an acceptable outcome from implementation of these proposals.

Under this approach, the APVMA's current preliminary assessment phase would become an administrative check of an application's completeness, which would not involve and technical assistance or evaluation.

CropLife welcomes this reform as a useful mechanism to improve the utility of the screening process. This approach puts the onus on applicants to ensure their applications meet the stated requirements of the regulator.

Many applicants outsource the preparation of their submissions to the APVMA to professional consultants, enabling even inexperienced applicants to provide high-quality applications that meet the technical and quality requirements necessary for the APVMA to conduct an efficient risk assessment and registration.

Implementation of this reform would positively impact on the technical resources of the APVMA, and result in freeing resources for risk assessment of applications after screening.

The option for the applicant to change the assessment category after lodgement would be removed.

CropLife could support this proposal, but notes that its effectiveness will be dependent on the successful implementation of other elements of the *Better Regulation* reform package, especially any potential implementation of pre-application assistance and comprehensive risk frameworks. While implementation is not supported at this time, this proposal should be revisited once comprehensive risk management frameworks have been developed. Greater clarity may preclude the need for this flexibility.

The APVMA would not assess efficacy or trade components for applications where there is a low risk from excluding these assessments.

CropLife would welcome greater detail about the sorts of applications where efficacy and trade components would not be required. In particular, the magnitude of risk is an outcome of the assessment process. However, it may be that there are certain classes of products (and some progress on this front has been made for veterinary products) that may not require full efficacy or trade risk assessments.

Greater detail will be required to outline those applications where the risk is low enough that these elements can be omitted from the risk assessment process. In developing any proposals along these lines, the Government should remain cognisant that efficacy data is often used for data protection purposes by registrants and resistance management strategies can also be assisted by the availability of sound efficacy data.

Timeframes would be amended to include the total elapsed time, from lodgement, assessment and arriving at a decision. Set extensions to timeframes, where requested would need to be mutually agreed between the APVMA and the applicant.

CropLife welcomes proposals that would give applicants greater certainty surrounding finalisation of their applications. CropLife notes that to ensure that the additional total elapsed time clock provides this certainty for applicants, there must be open and effective communication between applicants and the APVMA. CropLife would welcome further discussion surrounding the consequences of failing to meet the total elapsed time clock for both the regulator and the applicant.

CropLife could support this proposal if the sole consequences of not meeting the time clock were negative for the applicant. A process where failure to meet the total elapsed time clock by the APVMA resulted in a fee rebate could be considered.

CropLife supports proposals for mutually agreed extensions to the total elapsed time.

Consideration could be given to an optional accelerated assessment process. The extra resources required for this to operate would be generated from full-fee cost-recovery.

CropLife welcomes this proposal as an additional option for registrants, however, the design of this additional assessment option must be carefully considered to ensure these measures do not adversely impact on the existing application stream. CropLife would not support this proposal if the outcome was that the existing assessment performance of the APVMA was to decline in response to increasing demands from this process.

Care would need to be taken to ensure that, where an applicant decides this option would suit its application needs, resources from the APVMA's regulatory partners are in place to facilitate their timely consideration of health and environmental impacts.

CropLife also notes that there are certain aspects of the design of this application option that do not support regulatory efficiency. In particular, CropLife notes that application fees for expedited assessments would be approximately five times current rates on the basis that currently approximately 20% of the application fee is covered by the APVMA application fee.

CropLife has previously outlined its concerns surrounding the mix of fees and levies to support the operations of the APVMA. Our concerns are based on the fact that the over reliance on levy funds means that a few successful products end up subsidising the registration and assessment costs of the bulk of products that are not necessarily successful. Improved efficiency could be achieved by ensuring that a greater proportion of the true application cost is paid for by application fees rather than an ongoing sales levy. The outcome of such a change would be to create a direct link between the performance of the APVMA and its source of funding.

CropLife has also previously suggested that there should be mechanisms to ensure that once a product has paid sufficient sales levy to cover the cost of its registration, the levy should no longer be payable.

CropLife welcomes this proposal but notes that significant work still remains to ensure that the outstanding details regarding how this proposal could be implemented will have a significant impact on the likely benefits of an expedited assessment scheme.

3. Enhancing the agvet chemical review arrangements

It is proposed to introduce a new requirement to ensure that all agvet chemical approvals and registrations, including labels, are periodically checked against contemporary standards. This will put the onus on chemical companies to prove at regular intervals that their products remain safe.

CropLife strongly opposes implementation of a reconsideration program because:

- **There is no policy justification**

  The clear implication in the *Better Regulation* proposals is that there remain certain agricultural chemicals registered on the Australian market which have not been assessed against modern standards in terms of their human or environmental safety. This claim was advanced by the World Wide Fund for Nature (WWF) and the National Toxics Network (NTN) prior to the 2010 Federal Election campaign.

Given the National Registration Scheme has only been in place since 1995, there remain around 4,000 registered chemical products which were transferred to the APVMA at its time of formation. While it is true that many of these products have not been directly assessed by the APVMA, this does not infer that the safety of such products, and their active constituents, has not been properly assessed.

Prior to the formation of the APVMA, responsibility of the approval and clearance of active constituents, originally resided with the Technical Committee on Agricultural Chemicals (TCAC) and then from 1 July 1989, with the Australian Agricultural and Veterinary Chemicals Council (AAVCC).

During the late 1980s and early 1990s, the TCAC and then the AAVCC undertook a wide ranging process to review all of the Technical Grade Active Constituents (TGACs) registered in Australia. This process required registrants to provide comprehensive data in relation to the toxicity, metabolism, chemistry, environmental fate and environmental chemistry of registered active constituents, to allow the Committee to reaffirm that TGAC's continuing to meet necessary Australian standards.

This process broadly aligns with what took place in the US under the US EPA re-registration process at a similar time (http://www.epa.gov/oppsrrd1/reregistration/reregistration_facts.htm).

While there are instances where scientific understanding about a registered agricultural chemical can evolve, and scientific test methods are enhanced or regulatory standards change over time, necessitating targeted reconsideration, as is permitted under the APVMA's chemical review program. It is incorrect to state that there are large numbers of agricultural chemicals currently registered in Australia whose safety has never been properly assessed.

While there is certainly a strong policy basis to improve the timeliness, efficiency and quality of the APVMA Chemical Review Program, there appears no such basis to abandon Australia's risk-based review system, in favour of a hazard-based system which would require the reassessment, even at a minor level, of all registered products in Australia.

The importance of retaining a targeted risk-based review program, is accentuated by the resource constraints faced by the APVMA's Review Group, which arguably have impacted on the Authority's ability to make concerted progress in reviewing those active ingredients which have already been identified, by the Australian Department of Sustainability, Environment, Water, Population and Communities (DSEWPC) and the Office of Chemical Safety and Environmental Health (OCSEH), as Priority Candidates for Review on the basis of identified potential risks.

Once again, there appears a strong policy basis to review the APVMA's List of Priority Candidates for Review, and to improve the efficiency, timeliness and resourcing of the APVMA's Review Program, however it would seem illogical for the APVMA to be devoting its limited Review resources towards to assessing reapplications for the majority of products (where there is no evidence of possible risks has emerged during decades of use), particular when there remain 28 ongoing chemical reviews, and 41 actives identified as Priority Candidates for Review where reassessment is still to commence.

- **The consequences of this proposal are very likely to have significant negative impact on Australia's farming communities**

  Increased regulatory costs will result in some products being voluntarily withdrawn from the Australian market as the cost of supporting their continued registration exceeds the likely economic return. While there will be impacts on registrants from the potential loss of products, the impacts are likely to be significantly greater for farmers and other users.

Ensuring that farmers have availability to a range of safe and effective agricultural chemical products provides benefits through enabling robust resistance management strategies. Resistance management is a critical element of integrated pest management, and poor resistance management will ultimately result in increased pest pressure across a range of farming systems, affecting the productivity and profitability of several farmers.

Additionally, the extra cost of completing the new regulatory requirements will necessitate a re-examination of the cost of those products that are not voluntarily withdrawn. CropLife would expect that the costs of agricultural chemicals to users would be likely to increase.

Farmers would be impacted on two fronts. Firstly the cost of a significant input into modern farming systems will increase. Lesser product choice will decrease competition between chemical suppliers, also potentially resulting in increased costs. Secondly, the impact upon resistance management and increasing pest pressures will potentially reduce yields.

If there was an identifiable benefit in terms of worker safety, consumer protection or environmental health, CropLife could consider appropriate reforms to ensure that the appropriate protections are in place. However, CropLife is yet to receive any justification for why the existing approaches employed by the APVMA are inadequate.

It must be remembered that the APVMA (like farmers and chemical registrants) operate in a resource constrained environment. Where this is the case, it is far superior to identify products or active constituents requiring review by considering their risk. A risk based process, like the APVMA's Chemical Review Program, can consider the volume of use, the crops a product is applied to, as well as the intrinsic hazards of the active constituent. The benefit is that the resources dedicated to reviewing a chemical can be directed to those products that present the greatest risk.

CropLife does not agree that giving the APVMA an additional reconsideration process will generate positive benefits for chemical review. As several current review processes have been in train for over five years, creating additional processes is only likely to create longer lists of chemicals awaiting review, potentially delaying necessary actions that may be necessary to fully manage product risks.

- **There is insufficient detail about how these proposals will offer any benefit**

  Much greater detail is required regarding the standards against which chemicals are expected to be judged. Agricultural chemical registrants already demonstrate that their products do not present an unacceptable risk when used in accordance with the approved label directions, and are already legally required to advise the APVMA should new information become available that might impact upon the outcome of the risk assessment conducted by the APVMA under s161 of the Agvet Code.

  Without any information regarding what additional standard registrants are going to be expected to meet, it is difficult to provide any significant comment.

  Broadly, CropLife's view is that agricultural chemical regulation must provide additional benefits that outweigh the costs of additional regulation. For a reconsideration scheme, CropLife believes that there are only likely to be very minimal, if any, improvements in health, safety or environmental protection that can be achieved when compared to the existing requirements under s161 of the Agvet Code, the Adverse Experience Reporting Program and the current Chemical Review Program.

  Further, there is a significant potential that additional costs to the agricultural sector will be incurred through the voluntary withdrawal of agricultural chemicals by registrants. Where the costs of complying with vague additional regulatory requirements exceeds any potential income associated with that product, the product is likely to be voluntarily withdrawn from the market, irrespective of any health, safety or environmental concerns.

Additional data protection for information submitted by registrants would be a necessary addition to the package of proposals to ensure that some incentive for industry innovation remains. CropLife has long sought improvements in data protection to encourage industry innovation. Current arrangements to protect data developed by registrants through a review process are inadequate. CropLife has previously provided the federal government with recommended improvements to data protection and that would enable the generation of new data by encouraging collaboration among registrants. These are attached to this submission at **Attachment A.** These should be read in conjunction with CropLife's submission to DAFF in March 2010 regarding specific improvements for data protection surrounding chemical review. CropLife's submission is available at: http://www.croplifeaustralia.org.au/default.asp?V_DOC_ID=2322.

Set timeframes would be established for the submission of data and information in support of agvet chemical reviews. This aims to ensure that all required details are provided to the APVMA in a timely manner to facilitate more efficient assessment processes and to enable the finalisation of reviews.

CropLife supports measures designed to facilitate the finalisation of agricultural chemical reviews. However, one of the main reasons that chemical reviews take significant time for conclusion is that there is no incentive for registrants to promptly develop the data necessary to finalise a review. Indeed, there is often a commercial benefit from not providing information to a chemical review, but continuing to maintain a registration by free-riding on the data developed by competitors.

Without increasing the incentives for agricultural chemicals to develop the data necessary through a review process, there is a significant risk that chemicals will be lost from the Australian market not because of any environmental or health concerns, but due to a lack of any commercial incentive to support a product.

Set timeframes may not allow adequate time for negotiations between product registrants to collaborate to develop the new data necessary to justify continued registration. Flexibility will be required, as if only one registrant is required to produce new data, a much shorter timeframe could be considered. In contrast, where many registrants of the same active constituent exist, negotiations may be significantly drawn out.

CropLife believes that it is an important principle that registrants should be given a fair and just opportunity to demonstrate that their products can continue to be used with minimal risk to users, consumers and the environment. Set timeframes for the submission of data (when the development of data itself could take several years) may not provide an adequate opportunity for registrants in all circumstances.

The reform introduces sunset approval and registration provisions, in addition to the existing chemical review program which would continue to review chemicals based on risk.

CropLife does not support sunset provisions for the registration of agricultural chemicals. CropLife does not consider that these provisions will offer any benefit in terms of user safety, consumer protection or environmental health. For many products, where there is no additional information that indicates that a risk may not have been fully considered, a sunset on its registration status only serves to either remove a product from the market without justification, or require the registrant to progress through an additional administrative process without any benefit.

Proponents for sunset clauses will argue that arrangements of this type will present a trigger for review of a chemical product to ensure that contemporary standards are met. It will provide an opportunity for the regulator to check that registration of the product remains appropriate. However, this argument is not justified. If the APVMA or a registrant were to become aware of a new risk that had not been fully considered through a previous registration process, then the APVMA or the registrant would be negligent if it failed to take actions to address that additional risk at that time. CropLife would consider it to represent poor product stewardship if a product were continued to be marketed and sold in circumstances where legitimate concerns had not been fully examined. This should occur as soon as practicable after the concerns are raised and not wait for a regulatory check through a re-registration process.

A registrant's responsibilities with respect to new risks are outlined in s161 of the Agvet Code. That section provides that where registrants become aware of new information that may impact upon the risk assessment conducted by the APVMA, that it must provide that new information to the APVMA.

These arrangements, along with the existing Adverse Experience Reporting Program and the risk-based Chemical Review Program provide a superior, timely response when new issues are identified.

CropLife notes that the current regulatory system has been criticised by some organisations as requiring opponents to chemical use to prove harm from chemical use rather than requiring registrants to demonstrate safety. This criticism is not justified as registrants must demonstrate safety in accordance with established regulatory standards prior to product registration. Even after registration, the APVMA can, and does, examine new data and information that is available to it. If a group or organisation posits that a chemical or product is harmful or causing damage, they must provide some evidence to support that proposition. This can then be examined by the APVMA to determine whether a review, or some other action should be taken to reflect that additional risk. Again, these risks should be addressed as soon as they are identified, rather than being addressed at the end of any registration period.

The APVMA would not review a chemical registration if, after it gives notice that data or information is needed, that data or information is not forthcoming within a specified time.

As highlighted above, without providing the time and incentive for registrants to provide additional data or information, this will simply result in safe and effective chemicals being withdrawn from the market for commercial reasons.

CropLife believes that much of the current delays in finalising reviews by the APVMA could be ameliorated by improving the data protection provisions for data submitted under a chemical review. Positive approaches that encourage industry innovation and stewardship of products, rather than negative measures will deliver better outcomes for Australia's farmers in terms of chemical choice and price.

Reforms will introduce sunset approval and registration provisions in addition to the existing chemical review program which would continue to review chemicals based on risk. Information on which registrations require review and re-registration, would be informed by:

- Advice from registrants and manufacturers;
- Existing data and information where it remains relevant
- Overseas assessments where they are relevant; and
- Scientific advice.

As discussed previously, CropLife is concerned that these measures will not result in significant improvements in the way that agricultural chemicals are reviewed, and will instead introduce significant inefficiency into the Australian chemical review system. CropLife notes that this system will not *replace* the current risk-based chemical review system, rather it will operate in addition to it.

CropLife believes that only one system is required to address the review of agricultural chemicals. Two competing and potentially inconsistent systems will only serve to increase the regulatory burden upon registrants without any improvement in the level of environmental protection.

If shortcomings in the existing chemical review program are identified, these should be addressed through the existing chemical review system rather than by seeking to introduce a second system.

The information submitted to determine whether an agricultural chemical should be reviewed or re-registered under this program includes the same information that could be examined under the existing Chemical Review Program. As such, CropLife expects that re-registration reviews conducted under this process would be subject to the same constraints as the current Chemical Review Program. That is, without a comprehensive mechanism to encourage registrants to develop and submit new data or information, rapid conclusion of reviews is unlikely to occur.

Given that the current Chemical Review Program can take several years to produce a final review, there may be situations where a chemical is being reviewed under the existing program as well as progressing through a separate re-registration process. This is clearly an inefficient use of the APVMA's resources.

Prior to implementation, CropLife will be expecting to see a Regulation Impact Statement that specifically states the problem, considers options for addressing the problem and identifies the expected costs and benefits from each option.

4. Using overseas assessments to their full extent

This reform aims to change the legislation to encourage the APVMA and its regulatory partners to make more effective use of work conducted by comparable overseas agencies, which have applied a compatible approach, to the extent possible considering Australian conditions.

CropLife welcomes reforms designed to improve the use of overseas assessments and has long sought reforms to allow greater recognition of overseas assessments. CropLife does note that progress has been made with the implementation of Global Joint Review programs on this front, but considers that greater recognition of assessments that are relevant to Australian conditions could be achieved.

Consideration could be given to including contemporary scientific and technical standards that relate to agvet chemicals and the criteria that apply under the Stockholm and Rotterdam Conventions in the criteria that the APVMA applies when reviewing a chemical.

Under its current legislation, the APVMA has broad discretionary assessment powers. This enables it to apply contemporary assessment standards for new applications and chemical reviews. CropLife believes that this would include considering the standards applied by the Stockholm Convention on Persistent Organic Pollutants.

CropLife is aware, however, that the Rotterdam Convention does not assess chemicals. Instead, the Rotterdam Convention is merely a mechanism for participating countries to notify each other with respect to trade in hazardous chemicals (including pesticides). Listing under Rotterdam merely means that an active constituent is sufficiently hazardous to justify additional procedures for trade. It does not require any further action such as prohibitions on manufacture, trade or use.

The Rotterdam Convention does not employ any technical or scientific standards in its listing process. It is therefore inappropriate to consider listing under the Rotterdam Convention when reviewing a chemical.

While CropLife believes that the APVMA could consider the standards that are applied through the Stockholm listing process, CropLife would not accept the APVMA adopting Stockholm outcomes with respect to any particular chemical. The Stockholm Convention considers only the hazards of the active constituent and does not consider the risk of a formulated product with defined uses. Australia's current risk assessment processes remain superior to the Stockholm listing process. CropLife does note that any new chemical active constituent in highly unlikely to proceed through internal company screening for persistence or bioaccumulation potential.

CropLife is also concerned that the Stockholm process is increasingly becoming a forum for political campaigns against particular chemistries. In circumstances where decisions are not made on the basis of sound science, the APVMA should not be obliged to consider the outcome of the process.

5. Establishing an Independent Science Panel

The Government is considering establishing an independent panel of scientific experts to report on the APVMA's progress with reducing the backlog of reviews and improving the efficiency of assessments. It is not intended that they would review individual assessments.

CropLife does not support this proposal as it is currently outlined. However, CropLife would support the implementation of a panel to report on the APVMA's progress on increasing its efficiency and decreasing the backlog of product registration applications. However, more information on how any business review panel would be funded, and the likely benefit to be achieved is necessary.

The intended function of this panel is to review the performance of the APVMA in some specific areas, particularly the APVMA's progress in reducing the backlog of reviews and improving the efficiency of assessments. To adequately perform this function, it is not necessary to have scientific expertise. Rather, CropLife would recommend that this function could be served by regular external reporting on the APVMA's progress in improving the efficiency of its operations by an appropriately qualified business management organisation.

It may be more appropriate for any scientific advice sought by the APVMA to focus on ensuring that high scientific standards are adopted and maintained in the risk management framework proposed to be developed. The panel could also ensure that operational documentation consistently applies the standards identified in the risk management framework.

CropLife strongly supports the proposal that the independent science panel should not have a role in reviewing individual decisions. CropLife continues to believe that the APVMA must assess chemical applications in accordance with the established laws laid out by the Government. An additional ad-hoc review by an independent science panel will not provide applicants with the certainty they need to make business decisions. CropLife would be concerned that allowing review of individual decisions would open the science panel up to political interference. It may result in products having decisions made due to political pressure, rather than on the true risk of the product.

6. Enhancing the provision of expert advice

Removing the requirement for the APVMA to maintain an advisory board and replacing it with expert advisors would provide for a more efficient and effective way of providing the advisory function.

CropLife supports proposals designed to improve the efficiency of APVMA operations. CropLife notes that the advisory board has previously been identified as an area where efficiency improvements could be achieved. To that end, the proposal to replace the advisory board with expert advisors that could be brought in on an as needs basis to provide advice on specific defined issues is supported.

To a large extent, the APVMA's existing consultation mechanisms, especially the Industry Liaison Committee and Regulation Liaison Committee could be used to provide much of the expert advice and guidance to support the APVMA's operations. However, there may be circumstances where it is inappropriate to seek the advice of these consultative forums. In this case, there should be an opportunity to access further advice.

As for the proposals regarding the operation of an independent science panel, expert advice should not be sought on individual applications.

Expert advisors would be able to review issues and provide recommendations to the APVMA's CEO as required. The advisors would be utilised on an 'as needs' and flexible basis.

CropLife provisionally supports this proposal but more information is required. Care needs to be taken to ensure that individuals with acknowledged expertise are sought as expert advisors.

7. Improving legal interaction with the APVMA

Consultation on mechanisms to improve the capacity of the APVMA to respond to compliance issues fairly

As discussed below, CropLife welcomes a reconsideration of how agricultural chemical compliance can be better delivered. CropLife would welcome further discussion regarding procedural fairness around APVMA enforcement action where laws have been broken.

8. Improving the APVMA's compliance enforcement capacity

Providing the APVMA with a comprehensive, graduated and contemporary compliance and enforcement regime aims to fill the continuum in the existing compliance enforcement system to better manage compliance by tailoring penalty provisions to the degree and seriousness of the non-compliance.

Currently, the APVMA is responsible for managing compliance by agricultural chemical registrants. In addition, states and territories are responsible for managing compliance with rules and regulations associated with the use of agricultural chemicals. How compliance (by both Federal and state regulators) is delivered will be a critical issue being considered through consultations for a new national framework for agricultural and veterinary chemicals.

Proposals regarding the compliance functions of the APVMA will need to be carefully considered in the context of the national framework proposals for a nationally consistent scheme for agricultural and veterinary chemicals. In its submission to the *Discussion Paper on a National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals*, CropLife expressed the view that consideration should be given to withdrawing some, if not all, of the APVMA's compliance function to enable it to focus on continuing to provide high quality and timely risk assessments and registrations of agricultural chemicals. CropLife believes that the skills associated with operating a successful compliance activity are not necessarily consistent with those that are required to provide high quality risk assessments and registrations.

Irrespective of whatever administrative arrangements are put in place for providing a compliance function, CropLife supports the provision of an appropriate suite of tools to enable the compliance agency to tailor penalties to the magnitude or seriousness of the offence. However, it should be recognised that compliance involves more than the provision of appropriate penalties. Rather, it should involve a comprehensive program of monitoring, communicating and enforcing behaviour by registrants and users alike in accordance with established requirements.

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 (i.e. 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 an 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.