CropLife AUSTRALIA

SUBMISSION IN RESPONSE TO

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT BILL 2012

SECOND EXPOSURE DRAFT

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INTRODUCTION

CropLife Australia (CropLife) is the peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers, 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 and our member companies are global leaders in agricultural chemical product stewardship with end of life management of product and containers, resistance management and training and accreditation programs. CropLife member companies spend more than $13 million each year on stewardship activities to ensure the safe use of their products. 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.

The plant science industry's crop protection products include herbicides, insecticides and fungicides that are critical to maintaining and improving Australia's agricultural productivity to meet global food security challenges in coming decades. Each of these products is rigorously assessed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) to ensure they present no unacceptable risk to users, consumers and the environment. Without access to these tools, farmers may potentially lose as much as 50 per cent of their annual production to pests 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. Farmers demand these products because of the benefits they provide to their businesses. While it is important for governments to provide for appropriate regulation of pesticides, any regulation must be mindful of the effects that poorly considered and excessive regulation will have through increasing production costs, discouraging investment and innovation and delivering poorer safety, health and environmental outcomes.

The Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code) is the primary Act regulating agricultural chemicals in Australia. As a result, CropLife and our members have a strong interest in any proposed amendments to the Agvet Code. It is on this basis that CropLife has welcomed efforts to reform the Agvet Code to improve its efficiency, as well as improve the performance of the APVMA. CropLife welcomes the objective 'to cut red tape and increase the efficiency and effectiveness of agricultural and veterinary (agvet) chemicals regulation'[1]. Our members have long sought efficiency and performance improvements within the APVMA. We do, however, remain concerned that the reforms proposed fail to deliver any real efficiency or reduction in red tape. Indeed, our assessment of the Second Exposure Draft confirms that the Agvet Code will include additional functions and processes that are likely to further hinder efficiency aims and deliver no beneficial health, safety or environmental outcomes.

Continual unnecessary increases in the regulatory burden on applicants, registrants and approval holders will increase the total administrative and regulatory costs of the registration system, which may result in a loss of safe and useful products. At this stage CropLife must conclude that the promise of reductions in red tape and of a more efficient and effective regulator is merely a cover for a political policy agenda that will harm Australian agricultural producers, consumers and result in worse health, safety and environmental outcomes.

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

The consequence of increasing the regulatory burden is significant. Excessive and burdensome regulation will:

- Delay the introduction of innovative, modern agricultural chemical products for use by Australian farmers;
- Increase the costs of an essential farm input, with corresponding flow on impacts throughout the supply chain;
- Increase risks that safe, effective and affordable chemical products are withdrawn from the Australian market; and
- Exacerbate current issues with respect to minor uses of agricultural chemical products by increasing the regulatory barriers and corresponding costs of registering new and additional uses of products.

Access to fewer crop protection tools can facilitate faster development of resistance among target pests, diminishing the efficacy of remaining chemical options. The economic impact of weeds alone is estimated to be in excess of $4 billion each year, with an impact on the environment that is similar in magnitude[2].

Further, 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 per cent the cost to consumers of fresh fruit and vegetables. CropLife expects similar benefits to accrue to Australian consumers. Indeed an efficient and effective regulatory system that supports the introduction of modern crop protection technologies to improve Australian productivity would be likely to further reduce the cost of food to Australian consumers.

Agricultural chemicals are a core input for modern farming systems. They represent a cost effective, efficient and sustainable option for farmers to use to control pests, weeds and diseases. Increasing costs and red tape while potentially removing safe and effective products has the potential to make some production methods and farming businesses unsustainable.

Australia remains fortunate that it has some of the most advanced mechanisms to manage pest and weed resistance in the world. These resistance management schemes are a critical component of integrated pest management systems used by farmers every day. The systems rely on a range of chemical and non-chemical tools to prevent and delay resistance in pest and weed species. Chemicals with low use volumes, but with important resistance management roles, can have significant negative impacts should they be lost to Australian farmers.

CropLife sees appropriate regulation of agricultural chemicals as essential to providing the community with confidence that the food they eat is safe and that appropriate environmental protections are in place. However, inefficient regulation that will only exacerbate existing problems without providing any real benefit cannot be supported. CropLife remains disappointed that a genuine opportunity for reform has been missed.

Indeed, CropLife is disappointed that many of the recommendations it made in response to the first exposure draft in February 2012 appear to have been ignored. Greater consideration of the impact that particular reforms will have on Australian agriculture is expected through this process.

CropLife looks forward to working cooperatively with the Government to seek changes that will deliver on the original promise of the *Better Regulation* reform process.

CropLife reserves the right to revise or otherwise alter its position in relation to any issue as it considers additional information that is not available at this time. While some regulations are currently available, the consequences of all regulatory changes cannot be fully considered in the time available for comment on the second exposure draft.

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[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.

EXECUTIVE SUMMARY

CropLife welcomes the opportunity to consider reforms to the *Agricultural and Veterinary Chemicals Code Act*. While CropLife welcomes and supports those reforms that are intended to create a more efficient regulatory system that encourages agricultural innovation and productivity, it is disappointed that some of the key reforms promised by the Government do not appear to have been implemented in the exposure draft.

Further, CropLife remains disappointed that there is not one reduction in red tape as result of this process. Instead, new processes and bureaucratic procedures will increase regulatory burdens to the detriment of approval holders, registrants and potential new applicants. In turn these measures, as currently proposed, will have detrimental impacts on agricultural productivity in Australia.

CropLife is particularly concerned that some measures promised by the Government and explained in the summary document accompanying the second exposure draft do not appear in the draft legislation. Proposals to increase protection for information submitted as part of a chemical review for 10 years from the point when a decision is made, while promised, is absent. This apparent oversight raises doubts that other elements of the package may not be consistent with the advice received from the Government. It is indicative of a process that appears to be being rushed in an effort to meet artificial deadlines as opposed to fully considered and careful reform.

The limited time available for consultation has precluded CropLife's capacity to fully consider the implications of each and every amendment proposed, but this apparent oversight raises doubts that there may be other areas of reforms that have been overlooked, or that have unintended and unanticipated consequences that impose additional costs on the plant science industry.

These problems make it difficult to offer support for the package of amendments. Subject to recommended adjustments to specific provisions as outlined throughout this submission, CropLife does recognise that some reforms potentially offer benefits to CropLife members. These include:

- Process improvements for managing applications;
- Improvements to the APVMA's compliance tool box; and
- Improvements in data protection (where implemented).

However, CropLife remains concerned that these potential improvements will be outweighed by the administrative and bureaucratic cost of additional APVMA functions; including

- Re-approval and re-registration processes;
- Overseas regulatory triggers for Australian decision making; and
- Additional terminology that is vague, unclear and potentially damaging to regulatory efficiency.

Despite the *Better Regulation Partnership* being designed to provide benefits to industry, regulators and other stakeholders (including users of agricultural chemical products), no cost benefit analysis nor any other evidence has been presented to demonstrate that these reforms will deliver any net benefit. Indeed, CropLife has not been able to identify even one administrative or regulatory requirement that has been removed or reduced as a result of this process.

The significant number of missing reforms, reforms promised and not present, unrealistic implementation timeframes and the lack of any analysis of expected costs and benefits mean that CropLife cannot currently support this package of amendments.

CropLife, on behalf of its members have invested significant time, money and resources to assist Government deliver a package of reforms that result in better outcomes for the agricultural chemical registrants and agricultural industries more broadly. We remain concerned that despite our efforts to highlight a number of practical, achievable and relatively simple reforms that could be made to improve APVMA efficiency, the Government has committed to a course of action that will increase inefficiency and deliver poorer outcomes for all stakeholders.

CropLife remains frustrated and disappointed that, despite numerous representations, submissions and reviews over many years, several critical reforms to improve agricultural chemical regulation remain ignored and unaddressed. These missing critical reforms, and the lack of any serious attempt to investigate and document the costs and benefits associated with the reform package that has been presented seriously questions the commitment of the Government to providing the efficiency improvements long sought by the agricultural chemical industry.

CROPLIFE URGENTLY RECOMMENDS that:

- A cost benefit analysis is conducted to ensure that the package of amendments delivers a net benefit to the community;
- The proposed amendments in the exposure draft be subjected to a detailed review to ensure that they are consistent with the Government's stated outcomes; and
- Key efficiency and productivity reforms proposed by CropLife over several years are implemented.

These recommendations, along with the proposals recommended by CropLife throughout this submission are not minor in nature. To ensure that the package operates as intended, CropLife urges the Government to consider delaying commencement of these reforms. It is critical that they be subject to proper accountability and transparency procedures in advance of their implementation.

COMMENCEMENT AND IMPLEMENTATION

Successful implementation of these reforms will require a considered and thoughtful implementation strategy. The strategy currently proposed appears inadequate with insufficient consideration of how applications before the Australian Pesticides and Veterinary Medicines Authority (APVMA) on the date of commencement of these reforms will be dealt with.

CropLife seeks to ensure that no applications are materially disadvantaged by the commencement of the new Code. Ideally, this would mean that the APVMA would be required to assess applications made before 1 July 2013 in accordance with the current Agvet Code. CropLife does understand that this approach cannot be sustained indefinitely and would support a final transition to the new arrangements after a number of years of concurrent operation. The proposed 12-month transitional arrangements fail to recognise that the average time required for the APVMA to assess a new active constituent is currently nearly 3 years and 6 months.

CropLife is concerned that the exposure draft proposes that these amendments would commence from 1 July 2013. This is a completely unrealistic timeframe that does not recognise the practicalities of preparing and submitting an application for a new active constituent or chemical product. This is an unrealistic timeframe that puts at risk the entire reform program. Any benefits or efficiencies are jeopardised by an implementation plan that ignores the importance of having all supporting materials in place before streamlined processes commence.

While it takes time for the APVMA to assess an application, it also takes a significant amount of time for an applicant to prepare a high quality application that meets all the criteria for approval. This includes careful consideration of what information will be required to meet the legislative tests applied by the APVMA. CropLife members are currently preparing applications for submission to the APVMA after 1 July 2013. If these amendments commence from 1 July 2013 as currently proposed, then applicants will be preparing applications without full certainty of what will be required by the APVMA under new application requirements. It is for this reason that CropLife has strongly advocated for preparation and completion of the comprehensive risk framework well in advance of commencement. At this stage, the planned date for finalising the risk-framework is end 2014 which is unacceptable to deliver an effective regulatory system from 1 July 2013.

It will not be possible for applicants to adequately prepare applications without an understanding of the tests that will be applied and the information that will be necessary to satisfy regulatory requirements. If the objective of the comprehensive risk framework is to enable higher quality applications to be made, this outcome cannot be achieved as long as the framework describing how applicants are to meet the safety, efficacy and trade criteria is not available.

While the current Manual of Requirements and Guidelines presents a useful tool to advise applicants about the requirements that the APVMA expects, it is not sufficiently detailed to provide necessary information for the wide range of potential applications that the APVMA will need to assess. The problem is exacerbated when applications are sent to external agencies for health and environmental assessment advice. These agencies can, and do, impose additional requirements without fully consulting with affected stakeholders, including applicants.

The Government must consider delaying commencement and implementation of the reform package at least until a comprehensive risk framework can be developed in full consultation with all affected stakeholders. A delay to deliver the benefits of having all the necessary supporting documentation in place substantially outweigh the significant risk imposed by a hasty implementation to meet an artificial target date.

Delaying implementation would also allow time for the Government to assess proposed reforms to confirm that they will deliver net benefits to the community. CropLife remains sceptical that many of the proposed amendments will deliver any improvements in health, safety or environmental protection, and does not foresee significant improvements in APVMA performance efficiency. Indeed, these amendments generate a significant risk that necessary additional functions by the APVMA will further undermine the already unacceptable APVMA performance.

The only impact analysis that has been prepared to date was largely subjective, inaccurate and reliant on a series of presumptions about the legislated reforms that are no longer correct. Without an up-to-date and persuasive analysis to indicate that the significant costs associated with these reforms will deliver genuine health and environmental benefits, CropLife cannot support the package.

Indeed the expected costs associated with implementation of these reforms are a significant cause for concern for CropLife members. The Cost Recovery Discussion paper released in December 2011 highlighted that the expected ongoing increase in regulatory cost is expected to be at least $2.8 million each year. This includes $0.85 million for enhanced compliance activities and $1.95 million to support operation of the re-registration scheme[3]. While CropLife had understood that the cost recovery proposed in this Discussion Paper would not be applied until after the 'First-Principles' cost recovery process had been concluded, CropLife notes that the application fees proposed in the Discussion Paper do appear in the draft regulations released with this exposure draft legislation.

Until the precise nature of the ultimate package of reforms is finalised and the appropriate government response to cost recovery for the APVMA is determined, the level of fees and levies to be applied to APVMA functions should not be set.

CropLife recommends that implementation of the package of reforms be delayed to allow the comprehensive risk framework to be developed in advance of efficiency reforms commencing.

[3] APVMA Cost Recovery Discussion Paper p47

LINKS TO OTHER REFORM PROCESSES

Other reform processes will also have a significant impact on the APVMA's pre-market risk assessment functions. The concurrent COAG National Harmonisation process promises to increase the allowable off-label uses of agricultural chemical products. Should these reforms be implemented, the APVMA will need to reassess its approach to risk assessment of products, as the consequences of wider uses than those approved on the label could lead to significantly different risk assessment decisions by the Authority.

There is a significant risk that allowing off-label uses that have not been risk assessed by the APVMA will result in fewer products and active constituents registered for use by farmers. It remains unclear as to how any product could be considered to meet any safety, trade or efficacy criteria by the APVMA when its use is likely to occur in ways not considered or assessed by the APVMA.

This issue remains a significant concern for CropLife and our member companies who are committed to the responsible use of agricultural chemical products. Off-label use is inconsistent with this commitment.

At the very least, the comprehensive risk framework proposed to be issued by the APVMA must recognise the challenges that off-label use present to the risk assessment process. Without considering the consequences of the interaction between pre- and post-market regulatory activities, there is a significant risk that the policy settings established by the Agvet Code will be inconsistent with current approaches to control of use. A fully effective and efficient regulatory scheme must operate consistently throughout the whole agricultural chemical supply chain. This does not appear to be happening at the moment with significant dysfunction between federal and state approaches to regulating agricultural chemicals.

HAZARD AND RISK

Product risk based regulatory systems provide users with the greatest range of tools with which to manage their properties. Risk based systems also give users clear instructions on how the most important hazards associated with the product should be managed through clear label instructions for product use. CropLife continues to support risk management as the primary tool for regulating agricultural chemicals in Australia as the best way to take into account unique Australian circumstances.

CropLife supports the APVMA's current risk management approach to regulating agricultural chemical active constituents and products. CropLife understands that the Government remains committed to continuing to regulate agricultural chemical constituents and their associated products according to their risk. Regulatory 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.

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. Ultimately, active constituents are always formulated into a registered product before being used in Australia. The hazard and corresponding risk of an active constituent may be quite significantly different to the risk presented by a formulated and regulated product. Applying artificial hazard-based restrictions on products may ultimately result in poorer outcomes for farmers and the environment. For example, products are regularly formulated so that the intrinsic hazards associated with an active constituent are controlled to the point that they present little more than a remote or negligible risk. Excessive regulation of that remaining negligible risk may lead users to inadequately control more significant risks associated with that product.

CropLife is concerned that elements of hazard control are appearing in the Agvet Code and its subordinate regulations. While this does appear to be limited to calculation of timeframes for re-approval and re-registration, the precedent that this establishes moves Australia's system for regulating agricultural chemicals further away from best practice.

CropLife supports an appropriate level of caution when regulating agricultural chemical products. The APVMA's current approach means that hazardous active constituents may still be used in products in circumstances where the APVMA is satisfied that any risk to users, consumers or the environment can be safely managed with appropriate restrictions on use.

REVIEW OF OPERATION OF AMENDMENTS

Section 4 of the exposure draft requires the Minister to conduct a review of the proposed amendments within five years of commencement. While CropLife welcomes this review, it should not preclude a full assessment of the impact of these amendments in advance of implementation.

CropLife has already identified significant ongoing costs associated with these reforms. To date, CropLife remains unconvinced that these costs will be outweighed by any efficiency or productivity benefits from the reform package. This appears to be confirmed by the APVMA's Cost Recovery Discussion Paper[4] that indicates significant increases in the level of cost recovery sought from applicants and registrants, as well as the introduction of significant new processes and functions for the APVMA.

Further, CropLife remains unconvinced that there will be any broader health, safety, environmental or community benefits from these reforms. To date, no review has identified that the APVMA has not been effective in managing the risk to health, safety or the environment from agricultural chemicals. Indeed the core issue that has been identified by a number of reviews, (including those by the Australian National Audit Office and the Productivity Commission) is that the APVMA is inefficient in fulfilling its functions.

Attempts to build in additional functions to the existing regulatory process must be assessed to ensure that they deliver a net community benefit in advance of their commencement. It is unacceptable for the agricultural chemical industry to be subjected to additional regulatory inefficiency for no environmental or health benefit, when the core problem of regulatory inefficiency remains well recognised but unaddressed.

If the Government refuses to conduct a pre-implementation assessment of the proposed reforms, it must conduct a review of the operation of amendments within 12 months of implementation. To date, no independent and verifiable data has been presented that confirms that these reforms will deliver the benefits claimed. The proposed review to be conducted 5 years after commencement of reforms will be of little use if these reforms result in permanent, irreversible damage to a critical agricultural support industry. An early, 12 month review date will provide an opportunity to ensure that the reforms are operating as the Government intended and allow any necessary adjustments to be made rapidly.

[4] APVMA Cost Recovery Discussion paper p47

SCHEDULE 1—APPROVALS, REGISTRATIONS, PERMITS AND LICENCES

CropLife welcomes reforms that seek to improve and streamline the assessment of agricultural chemical products and active constituents in Australia. While many of the proposed amendments simply seek to update and restructure current legislative approaches, apparently subtle changes may have the capacity to significantly change the operation of the regulatory system.

The following comments are offered in relation to specific provisions:

- **Pre-application assistance**

  CropLife notes that it is the Government's intention to continue to provide pre-application assistance for applicants. Proposed regulations make it clear that the cost to applicants of any pre-application assistance (up to an established regulatory limit) would be recouped through a rebate on the application fee. This essentially amounts to the APVMA providing assistance to applicants preparing applications at no net cost to the applicant.

  CropLife understands the policy justification for pursuing pre-application assistance. It can assist applicants in preparing applications that are more likely to meet regulatory requirements. For some advanced, innovative and complex applications (eg: Category 1, 2 and Category 10 applications) there may be utility in allowing potential applicants and the regulator to discuss and clarify the content of an application and the assessment process in advance of an application being made.

  Most APVMA applications are straightforward and routine. Of the 1910 pesticide applications received in the 2011/12 financial year, 1618 were in 2-3 month assessment categories with an average determination period of 47 days elapsed time[5]. Use of pre-application assistance for simple applications is unnecessary and unlikely to represent an efficient use of the APVMA's resources. It may also undermine other measures designed to improve application quality. For example, investment in a comprehensive risk framework designed to improve applications will have little benefit if applicants can simply rely on APVMA pre-application assistance to determine what data and information will be needed for an application. Indeed, it is for those relatively straightforward applications that a risk framework could result in a substantial improvement in application quality.

  In contrast to making the APVMA more efficient, pre-application assistance could result in additional inefficiency. It entrenches cross-subsidisation between applicants and requires the APVMA to operate as a *de facto* consultant on applications. If the Government considers that it would be desirable to provide applicants with assistance in meeting regulatory requirements when preparing applications for the APVMA, this should either be:

  1. Managed through a specific program and funded from general revenue; or
  2. Fully cost recovered from those applicants that use the service. Users of pre-application assistance for simple applications should be required to pay the full cost of any assistance they receive from the APVMA, and should not receive any rebate on their application fee.

  There are a number of consultants and companies that provide specific services to support applicants prepare and submit applications to the APVMA. Requiring the APVMA to provide a similar service may result in a range of undesirable and anti-competitive impact upon these service providers.

  For more complex applications, pre-submission consultations between applicants and the APVMA may assist in ensuring that applications meet all the necessary regulatory requirements to facilitate a smooth and timely assessment. It is precisely these sorts of innovative and detailed applications that are least likely to be able to be fully addressed by a risk framework.

[5] APVMA Registration Statistics 2011/12- http://www.apvma.gov.au/about/reporting/docs/ag_2011-12.pdf p2

A streamlined system for improving application quality could include:

- Improving simple and straightforward applications by requiring them to rely on published guidelines and policies through the comprehensive risk framework, and denying access to rebateable pre-application assistance; and
- Improving complex and innovative applications through pre-application consultations to confirm assessment scope and clarify requirements.

This approach would result in a coherent process that efficiently uses APVMA resources where they are likely to deliver the greatest outcome.

CropLife recommends appropriate amendments to limit pre-application consultations to more complex and innovative types of applications.

- **1A - Implementing the Code**

CropLife accepts that the first priority of the regulatory system is the health and safety of people, animals and the environment. However, new concepts in the proposed new paragraph 1A(c) that require that the code be implemented in a manner that reflects 'contemporary principles' based on 'relevant science' are concerning.

Without understanding what 'contemporary principles' are intended to mean, it is difficult to consider what impact this may have on the current regulatory system. If there are specific contemporary principles that the Government wishes to apply, CropLife would welcome the opportunity to discuss these so that they may be expressly referred to within this paragraph.

CropLife would observe that the 'precautionary principle' is often cited with approval by many commentators. However, there is no broadly accepted definition of this principle to allow sufficient clarity required by a legislative reference. Indeed, it can be argued that this principle cannot be used for the assessment and management of risk as it seeks to eliminate risk by eliminating hazards instead of establishing appropriate and reasonable risk management measures.

The reference to 'relevant science' in the same paragraph raises similar questions. Without understanding the meaning and intent to base decisions on relevant science, CropLife cannot offer a position with respect to its appropriateness to the current regulatory scheme. CropLife is concerned that inclusion of vague terms might allow them to be interpreted in ways that are inconsistent with best practice risk assessment processes. Unless a clear reason for inclusion of an additional term like this can be raised, CropLife cannot support adding this term to the Agvet Code.

CropLife is similarly concerned by the reference to 'unmanageable risks' referred to in paragraph 1A(e). Ultimately, if the APVMA considers that the risks from a chemical product are unmanageable, then it already has the responsibility to not approve or register that product. CropLife is concerned that the phrase 'unmanageable risk' has been used to advocate for restrictions on chemical products even after they have been subject to a risk assessment by the APVMA, and approved. Ultimately, the final arbiter of what are manageable and unmanageable risks must be the APVMA.

CropLife recommends Section 1A be amended to remove references to 'relevant science', 'contemporary principles', and 'unmanageable' risks.

- **5A - Definition of meets the safety criteria**

  CropLife is concerned at the construction of the current test for meeting the safety criteria. Paragraph (1)(a) of this test requires any active or product to not be 'an undue hazard to the safety of people exposed to it'. Hazards are intrinsic qualities associated with a particular chemical, and are generally not quantifiable. An undue hazard is consequently unclear and imprecise. CropLife suggests that the word 'hazard' in this paragraph should be replaced with the word 'risk'. CropLife suspects that this amendment from hazard to risk more closely reflects the intention of the Government to restrict products that present an undue risk to the safety of people or the environment.

  CropLife recommends paragraph 5A(1)(a) be amended to replace the word 'hazard' with 'risk'.

- **6A - APVMA may make guidelines etc.**

  CropLife welcomes amendments to enable the APVMA to make guidelines. Effective, comprehensive guidelines are essential to providing certainty to applicants about the way that their application will be treated. While the current Manual of Requirements and Guidelines is useful, it is not specific nor detailed enough to effectively operate as a sufficient guide.

  APVMA guidelines must also apply to risk assessment advice sought from external agencies. Current practices whereby external agencies (the Department of Sustainability, Environment, Water, Population and Communities (DSEWPAC) and the Office of Chemical Safety and Environmental Health within the Department of Health (OCSEH)) can unilaterally revise requirements without adequate consultation with affected stakeholders are unacceptable.

  As previously argued, a comprehensive risk framework must be in place well in advance of commencement of the new Agvet Code. Applications scheduled for submission to the APVMA after 1 July 2013 are being prepared now, despite the lack of a comprehensive framework being in place. A smooth transition will be facilitated by ensuring that the risk framework is in place at the earliest possible juncture.

- **8C - Information to be taken into account in determining applications**

  CropLife welcomes appropriate measures to streamline the operation of the APVMA's assessments. This includes restricting the information that the APVMA can take into account when considering an application. Restricting the amount of information that the APVMA can consider prevents applicants constantly seeking to provide additional information and data to support an application and delaying assessment processes.

  This highlights how essential it is for the APVMA to clearly specify what information will be required in advance of these provisions commencing. Sufficiently detailed information on necessary requirements for the full scope of potential applications will be essential.

  Despite these measures, it is unlikely that the APVMA will be able to prepare guidelines that cover every potential application that it might receive. An appropriate level of flexibility will be essential to ensuring that the application process is capable of accommodating innovative new products.

  To this end, CropLife has previously recommended that some applications (especially applications for approval of a new active constituent) warrant some special considerations. It will be difficult for the APVMA to anticipate the sort of information and data that it may need to adequately assess a particularly innovative new active constituent. In these circumstances, a more collaborative approach may need to be adopted by both the APVMA and the applicant.

Without this additional flexibility, the APVMA may be restricted to applying an inappropriate risk assessment model that is unsuited to the innovative new product, resulting in a risk assessment outcome that is not ideal. The Government may wish to consider, at least for more complex application categories (such as for a new active constituent), whether greater flexibility in the information that the APVMA can take into account will result in better risk assessment outcomes.

CropLife does note that proposed regulations under this Act would specify the time period under which the APVMA must make a determination about a particular application. While time periods have been extended for all application classes, CropLife does note that special arrangements for global joint reviews and 'timeshift' applications have been developed. Provided that these approaches accommodate CropLife's concerns about specific types of complex and innovative applications, CropLife can accept the amendments.

Finally, the APVMA must continue to be able to accept scientific argument to address a particular concern. CropLife would welcome confirmation that the APVMA can continue to accept scientific argument or data in satisfaction of any information requirement.

CropLife recommends that for complex application categories, some flexibility in information that the APVMA can take into account is appropriate.

- **11 - Preliminary assessment (new approvals and registrations)**

CropLife welcomes and supports provisions that seek to improve the performance of the APVMA. The proposed new Section 11 seeks to achieve this by providing for a stricter process for a preliminary assessment. Currently, if the APVMA determines that an application does not contain all the required information for it to pass preliminary assessment it can delay consideration of that application while the applicant prepares additional data, or treat the application as having been withdrawn.

Under new requirements, if an application does not meet the application requirements, the application must be refused under sub-section 11(3).

CropLife is concerned that this new approach may have detrimental impacts in terms of data protection. Should an application be refused – even if refused because of an administrative oversight on the part of the applicant – CropLife seeks assurance that the value in any data submitted with that application is not lost.

This may become a greater issue as applicants and the APVMA seek process efficiencies through the Global Joint Review (GJR) process. Currently, the Organisation for Economic Co-operation and Development is developing an electronic data submission tool that will give all data required by all reviewing agencies globally to the APVMA. The APVMA will then apply a filter to access the data that it needs to identify the data that it needs for its purposes. Future data protection may be lost in circumstances where there are several products involved in the GJR, but not all are subject to an application to the APVMA. CropLife remains concerned that any protection value for that additional data may be lost should an applicant wish to use some of that additional data in support of a later application.

While CropLife understands that it is desirable from a policy perspective to discourage applicants from submitting additional data that is not strictly relevant to an application, CropLife would point out that in the case of GJR processes, the Australian applicant would only be relying on a section of the data provided to the APVMA via the GJR. Much of the data in relation to other products would have been received by the APVMA through its role as a GJR reviewer. Losing the protection value of that additional data would be a significant disincentive for any applicant to seek to use the GJR process.

Additionally, while CropLife welcomes measures that allow the APVMA to better manage applications, amendments that penalise applicants for APVMA failures are not supported. CropLife is concerned that sub-section 11(3) could operate such that if the APVMA is not able to complete a preliminary assessment within one month, the application must be refused. This would be an undesirable interpretation that would not be supported by CropLife.

CropLife also notes that under sub-section 11(4) the APVMA is only permitted to alter an application with the written consent of the applicant after it has passed preliminary assessment. While CropLife supports the APVMA having this power, CropLife does foresee some situations where, in the interests of efficiency, it may be beneficial to allow the APVMA to make some specific changes to an application before it has passed preliminary assessment.

In some circumstances, it can be very difficult to determine what application category applies to a particular application. While the risk framework would be expected to clarify the scope of application categories on most circumstances, CropLife anticipates that some uncertainty will remain. If the APVMA were to form a different view to the applicant on which category an application should fall under, the APVMA would be required to reject the application under sub-section 11(4). This problem may be exacerbated should the APVMA accept CropLife's recommendation that pre-application consultations should only be available to more complex, innovative application categories.

This concern could be remedied by allowing the APVMA to alter an application to, with the consent of the applicant, change an application category. Such a power should only be exercised by the APVMA in circumstances where it is more efficient and effective for the APVMA to change an application category than to reject the application.

This additional flexibility should improve APVMA flexibility and efficiency, but its limited nature would not allow any grossly deficient applications to proceed.

CropLife recommends appropriate amendments to section 11 to ensure that:

- Information made available to the APVMA via GJR processes does not lose data protection value only because an Australian applicant relies on a subset of that data in its own application;
- Applicants are not disadvantaged by having applications refused when the APVMA is unable to meet preliminary assessment timeframes; and
- Greater flexibility should be permitted to allow the APVMA to make amendments to application categories before an application passes preliminary review where it is efficient and effective to do so.

- **14 - Approval and registration**

Under the proposed new sub-section 14(2), the APVMA must refuse an application in circumstances where it cannot be convinced that an application meets the regulatory test within the defined timeframe. However, it should be a core principle of regulatory practice that an applicant should not be disadvantaged by failure of the APVMA, its external agencies or other regulatory processes to complete their processes on time.

For many years, CropLife has raised concerns about the impact that processes of external regulatory partners have on the capacity of the APVMA to meet its legislated timeframes. For example, new active constituents must obtain a scheduling decision from the Department of Health and Ageing. Despite efforts to streamline and improve their timeliness, scheduling processes have caused extensive delays. It would be unacceptable for an application to be refused by the APVMA in circumstances where the APVMA could not finalise an application because of delays due to other regulatory processes.

CropLife members have experienced delays of up to 18 months in securing a scheduling decision. As the scheduling process is completely outside the scope of APVMA influence, appropriate amendments must be put in place to ensure that applicants do not have applications unfairly refused due to external regulatory processes.

The APVMA will also be required to better manage its external agencies (DSEWPAC and OCSEH) to ensure that their assessments do not cause delays that will have unacceptable impacts upon an applicant.

CropLife recommends appropriate amendments to ensure applications are not denied due to delays caused by other regulatory processes that exceed the APVMA's timeframe for decision.

- **Division 2A —Varying prescribed relevant particulars**

  CropLife welcomes, and supports measures that will facilitate approval holders and registrants applying to the APVMA to vary prescribed relevant particulars of their approval or registration. In some circumstances, this will enhance the capacity of approval holders and registrants to ensure that the APVMA's record of approved products is consistent with that currently being produced.

  The capacity to vary relevant particulars must be supported with clear guidance (either within the risk framework or through other documentation) to allow applicants to understand what sort of variations to relevant particulars might be able to be made through this process.

  This process should remain as administratively simple as possible in order to encourage approval holders to use it. An excessively burdensome and bureaucratic process may operate as a disincentive for approval holders and registrants to vary particulars.

  Approval holders and registrants may seek to use this process to consider their need to vary relevant particulars in advance of any potential application for re-approval or re-registration. All necessary legislative instruments and clear guidance on the operation of these measures must be in place well in advance of the first approvals and registrations commencing through the re-approval and re-registration process.

- **27 - Applications**

  CropLife welcomes measures contained in sub-section 27 (2) to allow third parties to apply for variation of the relevant particulars or conditions of the registration of a product or approval of a label with the consent of the registrant or approval holder.

  This reform will facilitate permit progression onto labels and may also assist should any future minor use scheme be implemented. CropLife strongly supports the qualification that this should only occur in circumstances where the registrant or label approval holder consents to any variation of the label. This qualification is essential to ensure that approval holders maintain control of their label. As approval holders and registrants bear responsibility for the performance of their products under the Competition and Consumer Act 2010, it is essential that they retain the right not to accept any additional risk presented by a label variation.

- **28 - Preliminary assessment (varying relevant particulars and conditions)**

  Similar to comments in relation to Section 11, CropLife remains concerned about the potential loss of data protection resulting from measures to streamline application procedures. CropLife would welcome confirmation that the new Agvet Code will allow applicants to reclaim data submitted with an unsuccessful application for variation.

- **31 (2) and (3) - Reconsideration (requirements for APVMA to prepare a work plan)**

  CropLife supports measures to facilitate a more effective reconsideration process. Requiring the APVMA to prepare and maintain a work plan may assist approval holders, registrants and user groups to decide their level of engagement with any reconsideration process, and provide some certainty around that process.

  However, it will be important that the APVMA consults closely with affected registrants when developing a work plan, as a commitment to develop any necessary additional data will need to be coordinated with registrants to ensure that any proposed work plan is achievable and relevant.

  CropLife recommends an amendment that requires the APVMA to consult with all approval holders and registrants of a particular chemical product under reconsideration prior to finalising any work plan.

- **32 - Notice of reconsideration**

  CropLife supports those measures designed to improve the way that reconsideration processes are managed by the APVMA. CropLife does however remain concerned that these reforms may not address core problems that operate as a disincentive for approval holders and registrants to participate in a reconsideration process.

  While the clauses for providing notice about a reconsideration are welcomed, including the requirement that the APVMA must supply details of the work plan, incentives remain for approval holders and registrants to delay engaging in any review process.

  While CropLife understands the need for the APVMA to access existing information in a timely manner, the current proposal may impose obligations on approval holders and registrants that are both unnecessary, and difficult with which to comply. Requirements under Paragraph 32(1)(b) that require an approval holder or registrant to provide information of a kind stated in the APVMA notice may prove to be problematic. While an approval holder or registrant may be aware of information, that does not necessarily mean that the approval holder has either access to, or control of that information.

  CropLife objects to an offence being created where an approval holder or registrant fails to provide information to the APVMA when that information is not within their care or control.

  CropLife recommends that information should only be required to be provided to the APVMA by an approval holder or registrant where that information is under the care and control of that approval holder or registrant.

- **33 - APVMA may require information, reports, results or samples.**

  CropLife supports measures to require approval holders and registrants to submit relevant information, reports, results and samples. However, some adjustment of this section may assist in generating better responses from registrants.

  Currently, approval holders and registrants that choose not to participate in data generation activities suffer no penalty in relation to their approval or registration. Indeed, there is often a significant incentive for approval holders and registrants to delay decisions about participation in any data generation activities.

In a situation where the APVMA requires trials or laboratory experiments under Paragraph (1)(c), all approval holders and registrants should be given a limited opportunity to indicate that they will participate in any data generation or trial program. Approval holders and registrants that do not indicate they wish to participate must have their registrations and approvals cancelled. This will ensure that all approval holders and registrants share incentives and responsibilities in supporting an agricultural chemical in the market.

While the offence provision in sub-section (5) will provide an incentive, ensuring that only those approval holders and registrants with a commitment to developing data should be allowed to maintain their approval or registration. This will remove a significant disincentive for delaying participation in any data generation activities.

- **34A - Varying relevant particulars**

  CropLife supports the content of Section 34A to require the APVMA to vary relevant particulars or conditions in situations where doing so would satisfy the APVMA that an active constituent or product meets the relevant safety, trade and efficacy criteria.

- **110A - Preliminary assessment (permits)**

  In contrast to applications for approvals and registrations, re-approvals and re-registrations permit applicants may be given up to one month to rectify an application. If it is the intention of the APVMA to streamline the application process by limiting opportunities for applicants to rectify applications, then this principle should be applied to permits, as well as to applications for approvals and registrations. Given that permits represent a significant draw on the APVMA's resources, restricting opportunities to rectify permit applications may represent an opportunity to improve the performance of the regulator.

- **112A - APVMA may issue permit on its own initiative**

  CropLife supports introduction of a new power for the APVMA to issue a permit on its own initiative. However, this power must only be exercised with the consent of any affected approval holder or registrant. Approval holders and registrants bear product and reputational risk from the use of their products. Should an approval holder or registrant be concerned that a proposed permit may have unintended or unanticipated consequences, an approval holder or registrant must retain the right to prevent that permit from being issued.

  CropLife recommends that the proposed new Section 112A be amended so that permits may only be issued on the APVMA's own initiative with the consent of the registrant or approval holder.

- **156A - Giving information electronically**

  Measures to allow applicants, approval holders and registrants to give information to the APVMA electronically are welcomed. This is an overdue reform that has the potential to minimise the cost to the APVMA in handling information.

  Hard copies of documents should only be required where absolutely essential. Indeed, hard copies of applications should only be required where the applicant is unable to provide an electronic copy. If the handling, storage or use of hard copies imposes additional costs on the APVMA, these should also be recovered from the applicant. Additional cost recovery fees may be appropriate for applications that are only submitted in hard copy.

  CropLife recommends that hard copies of applications should only be accepted where the applicant is unable to provide an electronic copy.

- **160 - Overseas trials and experiments etc.**

  Reforms that enable the APVMA to, where appropriate, adopt decisions and evaluations made by overseas regulators are supported by CropLife. However, some restrictions about how the APVMA may consider overseas decisions and evaluations may be appropriate. Not all regulators make decisions in ways that are comparable to Australia's risk based processes. As has occurred in other areas of these reforms, it may be beneficial to expressly specify comparable regulators that make high quality risk based decisions in a similar manner to the APVMA.

  CropLife does recognise that new Paragraph (3)(d) of this section would require the APVMA to consider differences in the way that different regulators make decisions or evaluations. CropLife supports inclusion of this additional qualification.

- **165A - Period within which APVMA is to conclude reconsiderations**

  CropLife would urge caution when considering establishing timeframes for concluding reconsiderations. While timeframes may be useful for the APVMA in establishing work plans for finalising reconsiderations, establishing timeframes without understanding the reasons why existing reconsiderations take a long time to finalise may simply result in the cancellation of products that could be used safely and sustainably.

  Agricultural chemicals under reconsideration are often generic products well past any patent protection. This means there is often a large number of approval holders and registrants for any agricultural chemical that is to be reconsidered. Many of these approval holders and registrants have little interest in developing data to support ongoing approval or registrations, preferring instead to leave these tasks to other registrants.

  One of the key reasons for delays in reconsideration is the significant incentive that exists for approval holders and registrants to defer making a decision about planned involvement in any reconsideration process. Unless approval holders and registrants of active constituents and products under reconsideration are forced to declare their intention to support their product, delays will continue.

  CropLife would support defined periods for concluding reconsiderations on the provision that those approval holders and registrants that do not wish to participate in any information and data generation activities have their approvals and registrations cancelled once the data call in period expires. No product phase out should be necessary under these circumstances as approval holders and registrants are aware of the reconsideration process.

  Secondly, developing data is often a particularly time consuming process. In some circumstances, multi-year residue or efficacy data may be required to satisfy the APVMA that a particular active constituent or product meets the safety criteria. This could delay conclusion of the reconsideration beyond the permitted timeframe. CropLife would suggest that where approval holders and registrants that have committed to a work program to develop data for consideration by the APVMA in good faith, then the APVMA must retain the power to extend the time for conclusion to facilitate evaluation of any additional data.

SCHEDULE 2—RE-APPROVALS AND RE-REGISTRATIONS

CropLife remains concerned that proposals to introduce a scheme to re-approve active constituents and re-register products builds another layer of bureaucracy without providing any meaningful improvement in human health, safety or environmental protection. While CropLife understands that introduction of a re-approval and re-registration scheme was part of the commitment given prior to the 2010 election, it represents bad policy that should immediately be revised. The need for a re-approval and re-registration scheme stems from a false assumption that the APVMA is currently not properly managing its existing chemical product portfolio.

Reviews by the Productivity Commission and the Australian National Audit Office have confirmed that the APVMA has reasonable arrangements for identifying and prioritising existing chemicals requiring review.[6]

CropLife accepts that there are current problems with excessive delays under the APVMA's Existing Chemical Review Program. However, creating an additional bureaucratic process to sift, funnel and add additional chemical products to the existing review priority list will not help address concerns about the time taken to complete a reconsideration. It is concerning that the measures proposed in the second exposure draft appear not to be targeted at addressing the core problems associated with the current chemical review program. Instead, by creating 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.

A comprehensive risk framework describing the criteria through which active constituents and products would be assessed is essential. This is particularly the case when the new Section 1A introduces novel, undefined and imprecise concepts such as 'contemporary principles', 'relevant science' and 'unmanageable risks'. Approval holders and registrants require certainty about the standards against which their active constituents and products will be assessed. At this stage, no such standards are forthcoming from the Government.

The anticipated costs of a re-approval and re-registration scheme remain concerning to CropLife and its members. The Cost Recovery Discussion Paper released by the APVMA in December 2011 confirmed that it was expected that re-approvals and re-registrations would cost the APVMA approximately $2 million each year to administer. This does not include the costs to applicants required in preparing applications and meeting APVMA requirements which would be at least commensurate with (and would likely exceed) the APVMA's administrative cost. CropLife would expect to see corresponding improvements in health, safety or environmental benefits that make this investment worthwhile. Unfortunately, there appears to be little evidence that this will be the case. Indeed, additional bureaucratic and administrative functions required by the APVMA that do not assist in managing risks from products may ultimately result in distracting the APVMA from its essential core business of providing risk assessments, decisions and managing the existing chemical product portfolio.

While these core concerns about the utility and efficiency impacts of the re-approval and re-registration scheme remain, CropLife would continue to support the existing approach to identifying and prioritising chemicals for review. Ideally, improvements to the current chemical review system should focus on identifying and addressing the precise reasons why reviews are excessively delayed.

Despite CropLife's concerns about the effectiveness of the proposed re-approval and re-registration schemes, CropLife does offer the following comments in relation to specific amendments proposed in this exposure draft.

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6 Australian National Audit Office, 2006, Regulation of Pesticides and Veterinary Medicines, Australian Pesticides and Veterinary Medicines Authority, Audit report no. 14, Canberra.

- **29D Application**

  This section requires that applications for re-approval and re-registration must occur between six and three months before expiry of the approval or registration. While CropLife understands that the regulations may make provision for applications to also be made less than three months before expiry, there seems to be little justification for this restriction. CropLife would recommend that applications for re-approval and re-registration should be able to be made less than three months before expiry without penalty.

  The time that approval holders and registrants will require to prepare re-approval or re-registration application will be dependent upon the application requirements. At this stage, regulations under Section 8B, which would specify the information that must accompany an application have not been prepared, and the practicality of the application procedure cannot be verified.

- **29E Preliminary Assessment (re-approvals and re-registrations)**

  CropLife welcomes measures that allow the APVMA to better manage application processes. However, amendments that penalise applicants, approval holders and registrants for APVMA failures are not supported. CropLife is concerned that sub-section 29E(3) operates such that if the APVMA is not able to complete a preliminary assessment within two months, the application must be refused. This would be an undesirable interpretation that would not be supported by CropLife.

  Appropriate amendments that seek to ensure that where the APVMA is not able to meet its obligations under sub-section 29E(1), applicants are not disadvantaged through an unfair and inappropriate refusal of an application. Consistent with the discussion in response to changes to Section 11 of the Agvet Code, CropLife is concerned with the treatment of any commercially sensitive data that may be submitted with a re-approval or re-registration application where that application is refused.

- **29F Re-approval or re-registration**

  CropLife notes that this section introduces a new legislative test for re-approving active constituents and re-registering products. The new test that the APVMA must re-approve a constituent unless there are '*reasonable grounds to believe that the constituent* (or *product*) *does not meet the safety criteria'* is clearer and more specific than previous tests considered by the Government in the first exposure draft. However, CropLife still expresses concerns that the definition of *meets the safety criteria* includes an unacceptable and undesirable hazard element into the assessment. CropLife has discussed our concerns further in our discussion of the proposed new Section 5A.

  CropLife would welcome further consideration of what would amount to '*reasonable grounds*'. Greater understanding of the application of these terms will have a critical impact on the effectiveness of the re-registration and re-approval scheme. Inclusion of subjective elements of reasonableness may result in significantly increased uncertainty and regulatory risk for approval holders and registrants.

  When managing the safety, health, environmental and trade risks of agricultural chemical products in diverse and dynamic biological systems, there will always be some residual uncertainty about the performance of that product. The '*reasonable grounds to believe*' test must not be interpreted so that any grounds at all, no matter how remote or unrealistic, can be used to deny a re-registration decision.

CropLife recommends appropriate amendments to ensure that remote, unrealistic or merely hypothetical grounds do not justify the regulator refusing an application for re-registration.

CropLife does note that the same test is applied to all products irrespective of the hazards that their active constituents might present. As the APVMA can only refuse to re-register products where there are *'reasonable grounds to believe'* that the product does not meet the safety, trade or efficacy criteria, the justification for providing different re-registration periods for products is poor.

The proposed regulations seek to define the period for which a product or active would be reconsidered through a hazard matrix. This is in contravention of the Government's own stated policy, which committed it to establishing re-approval and re-registration periods on the basis of risk.

CropLife considers that this approach represents an unacceptable shift away from established risk management principles of Australia's regulatory system for chemicals management. Without a proper process based on the risk an active constituent or a product presents, the current process has the potential to impose greater regulatory costs on some products even in circumstances where they do not present any greater risk to health, safety or the environment.

Where active constituents and products meet the same regulatory standards (as they do through passing the same legislative tests) they should receive the same benefits. This would mean that each active constituent and product should be re-registered and re-approved for the same timeframe.

CropLife recommends amending the proposed section 29F so that that as long as the legislative tests are met, products and active constituents should be re-registered and re-approved for 15 years, unless new information is identified that would trigger re-approval or re-registration.

- **29G Varying relevant particulars and conditions to allow re-approval or re-registration**

  Requiring the APVMA to consider varying relevant particulars and conditions to allow re-approval or re-registration is supported by CropLife. This measure is consistent with existing provisions within the Agvet Code for reconsiderations and permits a level of flexibility in the way that the APVMA can administer its functions for the benefit of approval holders and registrants.

  Allowing this activity is also likely to minimise the number of active constituents and registrations that are ultimately referred for reconsideration.

- **47A Varying duration— decisions of foreign regulators**

  Ideally, the APVMA should be free to administer the Australian agricultural chemical portfolio in accordance with Australia's specific circumstances. Providing an additional trigger for products or active constituents to be re-registered or re-considered on the basis of overseas decisions is unlikely to change the practical outcomes in comparison to the current approach by the APVMA.

  At present, the APVMA monitors contemporary and comparable regulators around the world to identify regulatory decisions to determine whether they might have an impact on an Australian registered product or active. At any point in time, if the APVMA considers it necessary, a product or active constituent can be placed under review. The APVMA can do this if it identifies information not only resulting from a comparable regulator, but any other source as well.

  CropLife supports the proposal to prescribe comparable overseas regulators. This would preclude attempts to apply decisions from regulators with comprehensively different systems and circumstances onto an Australian context.

CropLife does note that one of the regulators proposed is the Chemicals Regulation Directorate of the Health and Safety Executive of the United Kingdom. This regulator is required to only register agricultural chemicals consistent with the European Union's Chemicals Agency (ECHA). As the largely hazard-based restrictions imposed by ECHA are inconsistent with Australia's risk-based system, decisions from the UK must not be included.

Some additional restrictions are required to ensure that this process does not inadvertently trigger additional, unnecessary re-registration and re-approval processes that are costly for the APVMA to administer and expensive for approval holders and registrants with which to comply. Certain decisions that should be excluded from being counted as one of the two overseas decisions would include:

- Decisions by overseas regulators that occurred before an active constituent or product was approved, re-approved, registered or re-registered by the APVMA must not be counted as one of the two overseas decisions. Any new information generated by that overseas decision would have been considered by the APVMA in the previous approval or registration decision. To allow that to count towards determining an additional re-approval or re-registration process is unnecessary.

- Decisions by overseas regulators that reveal no new information beyond that already considered by the APVMA should not be counted. If a decision by a foreign regulator makes a decision that relies on information or data that has already been considered by the APVMA, there is no justification to trigger an additional re-registration or re-approval process in Australia.

- Decisions by overseas regulators that relate to only a selection of Australian use patterns should not result in all Australian uses being subjected to an additional round of re-approval or re-registration. Only those uses that are commensurate with an overseas prohibition should be subjected to reconsideration by the APVMA. For example, decisions to prohibit use of a chemical used as an antifouling paint should not justify a decision to re-register herbicide uses of the same active constituent.

- Decisions by overseas regulators to prohibit or restrict a chemical on the basis of a product not being able to meet some arbitrary (non-risk determined) end-point must also not be counted. For example, failure of a product to meet the European Union's 0.1ppb restriction for residues in water must not be counted as one of the two decisions by overseas regulators.

CropLife does, however, support limiting consideration only to those decisions that have been made because of a concern about health, safety or environmental impacts while also taking into consideration differences in regulatory systems between regulators. Differences in the registration status of agricultural chemicals in different countries are often mainly driven by commercial decisions of chemical registrants. Often agricultural chemical registrations can lapse without any concern about their health, safety or environmental concerns. These commercial decisions made by companies must not be a trigger for regulatory action by the APVMA.

CropLife recommends appropriate amendments to exclude certain overseas decisions from counting towards triggering a re-approval and re-registration. Decisions that must not count include:

- Decisions that occurred before an active constituent or product was approved, reapproved, registered or re-registered;
- Decisions that do not reveal new information;
- Decisions that do not relate to Australian use patterns; and
- Decisions based on arbitrary end-points.

- **47B Advance notice of end of approval or registration**

  CropLife supports measures to provide for notice – both publicly and to registrants and approval holders – about the end of an active constituent approval or end of a product registration. This process will allow both users and registrants to consider their options for either seeking re-approval or re-registration, or to invest in development and approval of alternative tools that meet their needs.

SCHEDULE 3—ENFORCEMENT

CropLife supports the expanded compliance 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 compliance tools that enable proportionate responses to compliance issues will be increasingly important. An effective compliance regime must ensure that the APVMA is not excessively focussed on technical compliance by registrants, but focussed on compliance by the entire industry, including those seeking to avoid regulatory controls.

Importantly, the APVMA must seek to deploy its scarce monitoring, compliance and enforcement resources in a manner that allows it to focus its resources on those individuals and organisations that present the greatest risk.

Controlling and monitoring Australia's agricultural chemical portfolio is an administratively complex task for the APVMA, as well as for approval holders 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 of an active constituent source without notifying the APVMA, that registrant could be in breach of the Agvet Code. Provided that the breach has no effect on the health or safety of the products being supplied to Australian users, CropLife would not support excessive sanctions being imposed. It remains critical that any penalties imposed must reflect the risk of harm that results from any breach.

CropLife welcomes the focus on ensuring that the APVMA has adequate compliance powers. This needs to be matched by an enhanced strategic attitude towards compliance. Most compliance effort and resources should be focussed on individuals and organisations that seek to avoid regulatory scrutiny by deliberately avoiding compliance with the Agvet Code. In particular, significant compliance effort should be focussed on those that seek to import and supply products directly, avoiding registration requirements.

AGVET CODE

- **35A - Suspension or cancellation of registration if imminent risk of death, serious injury or serious illness**

  CropLife supports the APVMA having all necessary powers to properly manage the agricultural chemical portfolio. CropLife recognises the need for the APVMA to be able to suspend or cancel a product in circumstances where there is an imminent risk of death, serious injury or illness, or intentionally providing false or misleading information to the APVMA. This would not preclude the APVMA from taking other regulatory or compliance action, such as recalls or reconsidering an active constituent or product.

  This provision does highlight the interaction between the pre-market registration system and the various control of use regimes in place in states and territories around Australia. Under this section, the APVMA may suspend or cancel a product because of use practices that may be permitted by state and territory use regulations, but that were not assessed by the APVMA at registration. This represents a significant risk borne by registrants and ultimately a much more strict compliance regime may be necessary to ensure that this provision operates as intended.

- **Subsection 46(2)**

  CropLife notes that this new provision would require the APVMA to not only notify any interested person about a decision to revoke a suspension or cancellation, but to also place a notice in the *Gazette* about such a revocation. CropLife supports the requirement to publish a decision to revoke a cancellation or suspension.

- **131AA Monitoring powers to prevent imminent risk of death or serious injury or illness**

  CropLife supports measures to allow the APVMA to take appropriate action to manage the agricultural chemical product portfolio. As this provision will provide appropriate inspection powers to APVMA inspectors in exercising their responsibilities, CropLife supports the amendment.

- **Counterfeit product offences**

  CropLife notes that removal of offences relating to counterfeit active constituents and products. While CropLife understands the reasoning suggested that these offences are now covered by revised definitions of '*registered chemical product'* and *'approved active constituent'* under sub-section 3(1) of the Agvet Code, it will still be important to send a strong signal that counterfeit products remain illegal in Australia.

  To date, CropLife has been concerned that the APVMA has been too focussed on 'technical' compliance functions that target existing registrants to the detriment of those individuals and organisations seeking to illicitly import large quantities of unregistered and counterfeit products. Including a specific offence in relation to counterfeit products would send a strong signal that these sorts of products are illegal and unwanted in Australia, as well as providing the APVMA with a new compliance focus on counterfeit products. Such a focus is consistent with enabling the APVMA to address those compliance risks that that are most likely to have serious impact on health safety and the environment.

  CropLife recommends reinstating the counterfeit product offence provision.

- **Agents**

  Under new compliance and enforcement powers, the APVMA is able to impose penalties and issue infringement notices to the authorised agent for a product registered by an overseas company. However, a local agent may not be aware of all the correspondence sent between the APVMA and the registrant. Indeed, it is usually appropriate that an agent would not be directly involved in the business planning of an overseas company for Australian market products.

  If an overseas registrant commits an offence, the APVMA may decide to issue their domestic agent with an infringement notice. The agent may then be liable for paying any penalty specified in the infringement notice even when they may not have had any knowledge or control of the actions of the registrant or approval holder. Further, a domestic agent is likely to have very little capacity to recover costs from an overseas registrant or approval holder.

  The government could consider whether it would be appropriate to amend the exposure draft so that overseas registrants and approval holders could have registrations and approvals cancelled or suspended rather than imposing fines on their domestic agents.

SCHEDULE 4—DATA PROTECTION

CropLife supports and welcomes proposals for enhanced data protection, which will improve the incentive for innovators to bring newer, safer and softer chemical products to Australia. Appropriate data protection measures should also be able to facilitate better cooperation and collaboration between product registrants, approval holders and user groups. Both have an interest in ensuring access to a range of safe, affordable and effective pest and weed control options.

In particular, CropLife welcomes improvements in data protection for new active constituents and new products being extended to 10 years. This will improve the incentive for approval holders and registrants to bring newer, innovative products to Australia. This reform is also essential to make agricultural chemical data protection provisions competitive with other comparable international markets.

CropLife also welcomes provisions to more equitably treat innovative registrants of new agricultural chemical products and their generic competitors through better managing the issues related to spring-boarding applications.

It is still concerning that many of the measures that CropLife has proposed to enhance the data protection provisions for data submitted as part of a review remain unaddressed. CropLife is also concerned that some amendments would have the practical effect of diminishing the current level of protection for protected information submitted as part of a chemical review. Indeed, other measures necessary to encourage participation in data protection taskforces for active constituents and registered products under review remain absent. Until these can be fixed, CropLife is concerned that there will be no incentive to encourage product registrants and approval holders to develop necessary data for chemical reviews. Significant loopholes for approval holders and product registrants to delay involvement and 'wait and see' how chemical reviews progress will remain. This currently results in a significant market failure as these approval holders are not bearing the same costs as those participating in data generation. Data protection provisions are unable to address any lost business during the review phase.

- **Protection for data submitted in relation to a chemical review.**

  While CropLife welcomes the Government's intention to improve the protection period for data submitted under a chemical review, amendments to this effect do not appear in the second exposure draft. Confirming that data submitted under review will be protected for 10 years after a decision in relation to that review is made will be essential in assisting in providing an incentive for approval holders and registrants to develop any necessary data required to complete a chemical review process. The definitions of *protected information* and *protection period* confirm that the protection period remains at 8 years from the data of submission to the APVMA.

  Reforms to correct this oversight are urgently required. CropLife is troubled that such a key reform for supporting the reconsideration process appears to have been overlooked.

- **Subsection 3(1) - Definitions of *protected information* and *protection period***

  These two definitions specify the protection for information and data provided to the APVMA under reconsideration. These paragraphs specify that:

  - Any information specified under a Notice of Reconsideration received from the APVMA (Paragraph 32(1)(b)); or
  - Any information, results, reports or samples requested in a written notice received from the APVMA (Paragraph 33(1)(a)); or
  - Any trials or laboratory experiments conducted upon request of the APMVA (Paragraph 33(1)(c)),

  would be protected for a period of 8 years from the day that the information was presented to the APVMA.

For as long as competing products remain on the Australian market, the protection value of any information or data submitted to the APVMA as part of a reconsideration process, is nil. Further, any potential protection value is gradually diminished the longer the APVMA takes to finalise any reconsideration decision. Better protection for information and data submitted under reconsideration must be confirmed through two specific amendments, namely:

1. The protection period for information provided under a reconsideration must commence when the APVMA makes a decision to affirm the approval or registration of an active constituent or product under review; and
2. The protection period should run for 10 years for consistency with information presented to the APVMA under Sections 10 or 27.

CropLife notes that the summary document is inconsistent with the current draft in respect of this point. Consequential amendments to Paragraphs 59(2)(c) and 61(2)(d) will also be required to confirm that the protection period commences when the APVMA makes a decision, as opposed to when it receives the information or data.

CropLife recommends appropriate amendments to ensure that data submitted to the APVMA as part of a reconsideration is protected for a period of 10 years from the date the APVMA makes a decision.

- **Division 4A - Limits on use of information**

  CropLife supports those amendments to Division-4A that allow information presented to the APVMA in connection with an application under Sections 10, 27 or 161 to be protected in accordance with the provisions of this Division. In particular, CropLife notes that this Division will operate so that even if an application is denied, information may be protected unless it is also subject to one of the exemption categories specified in the proposed new Section 34J.

- **Sub-section 59(1)A**

  Any information provided to the APVMA to satisfy a regulatory requirement is potentially commercially valuable to the provider of that information. As a result, all efforts should be made to ensure that the data or information provided should not be used for the benefit of competitors. This is particularly the case for re-approvals and re-registrations where a number of applications for re-approval and re-registration would be considered at the same time.

  Section 59 restricts the capacity of the APVMA to use information provided to it under a review to approve or register competitive active constituents or products, and outlines the availability of compensation in circumstances where a subsequent applicant seeks to rely on information provided under a chemical review process.

- **Retain data protection for information associated with withdrawn or denied applications**

  Even if an application is withdrawn or denied, much of the data that the applicant submitted would be valuable for a future application or submission to the APVMA. This is particularly the case when an application is supported by multiple independent data sets that are not only relevant to a withdrawn or declined application, but any number of other applications that could be supported by other elements of that data set. Protecting data, even when the APVMA has declined an application is an essential driver for innovation.

  While CropLife understands that it is the intention of the Government to provide for protection of data even when applications have been received, currently, it does not appear that any necessary amendments are in place to deliver this outcome. CropLife would welcome the opportunity to discuss what further amendments would be necessary to deliver this necessary reform.

SCHEDULE 5—ARRANGEMENTS FOR COLLECTING LEVY

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

CropLife looks forward to working with the Government to investigate and identify the most efficient administrative arrangements for collecting the levy.

MISSING REFORMS

Increasing the efficiency and effectiveness of the APVMA requires a comprehensive reassessment of all its functions to ensure that they remain relevant to the objective of the legislation. After nearly 20 years of operational amendments and interpretations, some processes, legislative rights and obligations could be reduced or removed with no net reduction in the level of health, safety or environmental protection associated with the use of agricultural chemical products. Indeed, reducing regulatory requirements can improve health, safety and environmental protections by ensuring that scarce regulatory resources are not wasted on functions that deliver only marginal (if any) improvement in health, safety or environmental outcomes.

CropLife has previously suggested a range of reforms that could have been addressed through the *Better Regulation* reform process. Some of these have been considered and addressed as legislative reforms have been developed. However, there remains a set of reforms that CropLife has promoted over several years that are not currently included in the package of reforms. Reforms reducing the regulatory burden for applicants, approval holders and registrants will be necessary to redress some of the increases in regulatory cost associated with new processes such as re-registration and re-approval. Other reforms are now necessary due to 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, swimming pool chemicals and cleaners may not be most appropriately regulated by the APVMA and may be more appropriately controlled by another agency, if necessary. Removing these products from the APVMA's regulatory scheme will allow it to focus its resources on its core business of assessing, approving and registering agricultural and veterinary active constituents and products.
- **Clarifying obligation regarding the export of agricultural chemicals exported under permit :** Currently, some agricultural 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 Agvet Code and are therefore potentially subject to a sales levy. As the APVMA has almost no role in the compliance obligations related to products that are exported for use in other countries, collecting a sales levy is unnecessary. Specific amendments to ensure that products that are exported do not draw a sales levy should be introduced through this process.
- **Mechanisms to facilitate participation by all registrants and/or approval holders in generating data for active constituents and registered products that are placed under review :** As discussed elsewhere in this submission, this includes mechanisms to encourage all approval holders and product registrants to participate in data generation activities at an early stage of the chemical review process by removing the incentive to delay decisions to generate additional data.
- **Disbanding the APVMA Advisory Board:** Currently this Board serves no useful purpose yet drains APVMA resources through providing sitting fees and secretariat services. Its removal would free those resources to be redirected towards core APVMA functions.

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. 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 Authority'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.

CONCLUSION

CropLife's assessment of the second exposure draft highlights that the publicly stated goals of reform are significantly different to what the reform is delivering. In contrast to a streamlined, effective regulator that is capable of delivering more timely risk assessments, approvals and registrations, the suite of reforms will result in additional APVMA functions for no demonstrated health, safety, environmental or economic benefits.

CropLife is disappointed that even simple efficiency reforms proposed by CropLife since the beginning of this process have been ignored. CropLife notes that the Government is seeking to make Australia a regional food superpower and developing a National Food Plan to help deliver this outcome. It is incongruous that at the same time as pursuing these activities, the government is seeking to undermine a key supporting industry to Australian agriculture. The potential consequence of getting agricultural chemical regulation wrong will have consequences throughout Australian agriculture.

CropLife remains eager to assist the government deliver real reforms that benefit all stakeholders, and will assist in delivering government objectives through the National Food Plan. This will require a significant reconsideration of many of the regulatory responses proposed in the current exposure draft.