CropLife AUSTRALIA

SUBMISSION IN RESPONSE TO

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (REMOVING RE-APPROVAL AND RE-REGISTRATION) BILL 2013

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 and formulators of chemical crop protection products and agricultural biotechnologies. The plant science industry provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies that are key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $17.6 billion a year to the Australian economy and directly employs thousands of people across the country. CropLife Australia is a member of CropLife Asia and part of the CropLife International Federation of 91 national associations globally.

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

The plant science industry's crop protection products include herbicides, insecticides and fungicides that are critical to maintaining and improving Australia's agricultural productivity and meeting the global food security challenges of the coming decades. Each of these products is rigorously assessed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) to ensure they present no unacceptable risk to users, consumers and the environment. CropLife member companies contribute more than 140,000 compounds to discover just one useful crop protection compound. Once found, each prospective new product is thoroughly tested over a 10 year period at a cost of more than $250 million (US) before being submitted for registration and released to the market. Without access to these tools, farmers may potentially lose as much as 50 per cent of their annual crop production to pests, weeds and diseases.

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 require 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.

It is in this context that the plant science industry supports this Bill and looks forward to its passage through the Parliament as a matter of urgency.

REMOVING RE-APPROVAL AND RE-REGISTRATION

Re-approval and re-registration would apply increases in regulatory burden on applicants, registrants and approval holders that would increase the total administrative and regulatory costs of the registration system without providing any meaningful improvement in human health, safety or environmental protection. Likely outcomes of increasing the regulatory burden would be:

- Delayed introduction of innovative, modern agricultural chemical products for use by Australian farmers;
- Increased costs of an essential farm input, with corresponding flow on impacts throughout the supply chain;
- An increased risk that safe, effective and affordable chemical products are withdrawn from the Australian market; and
- An exacerbation of 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 would 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[1].

Further, the responsible use of agricultural chemicals generates direct benefits for consumers. According to the Deloitte Access Economics report released by CropLife Australia in November 2013, 68 per cent of the total value of Australian crop production can be attributed to the use of crop protection products. 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. 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 in that it has some of the most advanced mechanisms to manage pest and weed resistance in the world. CropLife's Resistance Management Review Groups annually develop Resistance Management Strategies for herbicides, insecticides and fungicides that are an important tool in assisting farmers manage this resistance. These strategies 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. There could be significant negative impacts should chemicals with low use or sales volumes, but with important resistance management roles, 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. Inefficient regulation that will only exacerbate existing problems without providing any real benefit should be removed and this Bill commences that process.

Re-approval and re-registration represent bad policy that stemmed from a false assumption that the previous legislative framework of the Australian Pesticides and Veterinary Medicines Authority (APVMA) did not allow for the proper management of the existing chemical product portfolio. Reviews by the Productivity Commission and the Australian National Audit Office have confirmed that the APVMA has reasonable arrangements in place for identifying and prioritising existing chemicals requiring review[2].

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1 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.

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

CropLife continues to support the existing approach to identifying and prioritising chemicals for review. Improvements to the current chemical review system could be achieved by focussing on identifying and addressing the precise reasons why reviews are excessively delayed. The creation of an additional and arbitrary bureaucratic process through re-approval and re-registration to sift, funnel and add additional chemical products to the existing review priority list would not address concerns about the time taken to complete a re-consideration. In fact, such a measure is likely to compound the problem as has been the experience of the European example. The re-approval and re-registration requirements fail to address the core problems associated with the current chemical review program. Instead, they would add additional bureaucracy and inefficiency through ill-considered processes, which would likely result in less capacity within the APVMA to deliver timely, high quality chemical reviews.

REMOVING TRIGGERS BASED ON DECISIONS BY FOREIGN REGULATORS

CropLife supports the removal of the additional trigger requiring chemical products or active constituents to be re-registered or re-considered on the basis of two or more decisions by overseas regulators. The APVMA should be free to administer the Australian agricultural chemical portfolio in accordance with Australia's specific circumstances.

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 from any other source as well.

RENEWAL OF REGISTRATIONS

CropLife supports reducing red tape by allowing for less frequent registration renewals of agricultural chemical products. This initiative will streamline the APVMA's administrative workload enabling it to focus on core business, which is registering chemical products. Due to different chemical products having differing commercial drivers, there is a need to have both annual and multiple year renewal of registration options. There will always be the case where products are intended to be superseded in the short to medium term. By only having multiple year renewal periods available, refunds of renewal fees or unacceptable renewal fees for products with a limited future would be required. Therefore, to encourage innovation by allowing for the flexible management of chemical product renewals, both annual and multiple year renewal of registration options are required.

CHEMICAL PRODUCT QUALITY

CropLife is supportive of amendments that provide meaningful improvements in human health, safety or environmental protection. Whilst re-approval and re-registration are examples of additional legislative burden without any such improvements, improving the capacity for the APVMA to secure information about the safety of chemicals supplied in the market is. CropLife supports the APVMA having all necessary powers to properly manage the agricultural chemical portfolio.

Improving the APVMA's compliance toolkit should allow the Authority to more effectively deploy its monitoring, compliance and enforcement resources on those individuals and organisations that present the greatest risk. It is therefore important that the APVMA is not excessively focussed on technical compliance by registrants but rather, focussed on compliance by the entire industry, including those seeking to avoid regulatory controls and those who do not adhere to the full particulars of their respective registrations.

VARIATIONS TO APPROVALS AND REGISTRATIONS

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 the APVMA's record of approved products is in line with that currently being produced and sold.

The capacity to vary relevant particulars must be supported with clear guidance to allow applicants to understand what sort of variations to relevant particulars might be able to be made through this process. Initial consultation with the Department of Agriculture in respect of this issue has been encouraging, but it is important that this process is as administratively simple as possible in order to encourage its use by approval holders. An excessively burdensome and bureaucratic process may operate as a disincentive for approval holders and registrants to vary particulars.

ACTIVE CONSTITUENT ANNUAL RETURNS

CropLife welcomes the recognition that annual reporting of import, export and manufacture of active constituents that are not made into chemical products is not required to operate the national scheme for regulating agricultural chemicals. CropLife does though, question the relevance of collecting returns on the import, export and manufacture of active constituents that are made into chemical products, considering the returns do not easily extrapolate to the APVMA's sales levy revenue. The first-principles review of the APVMA's cost recovery arrangements may and should identify further efficiencies in this area.

ELECTRONIC LODGEMENT OF INFORMATION AND FEES

Measures to allow applicants, approval holders and registrants to electronically provide information to the APVMA 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.

ACCESS TO INFORMATION

CropLife members are committed to not unnecessarily using the *Freedom of Information Act* (FOI), which requires the APVMA to act as a pseudo filing system, due to recognising the drain on the APVMA's limited resources which further inhibited the Authority's ability to achieve core outcomes. CropLife, therefore, welcomes amendments that 'turn off' FOI and instead allow the APVMA to fully recoup the costs involved in providing requested data whilst also providing an incentive for registrants and approval holders to more effectively manage their own data.

OTHER AMENDMENTS

CropLife welcomes all the amendments provided for in the Exposure Draft Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2013. It is important though to note that there are further reforms that should be implemented to improve and streamline the assessment of agricultural chemical products and active constituents in Australia that have been detailed in previous CropLife submissions throughout the *Better Regulations* reform agenda. A summary of these recommended amendments is as follows:

- **Pre-application assistance:** Pre-application assistance for simple applications is unnecessary, an inefficient use of APVMA resources and should be limited to more complex and innovative types of applications. For simple applications, the regulatory guidelines must provide adequate guidance to allow an applicant to submit a fully compliant application otherwise the utility of the regulatory guidelines needs to be questioned. Professional registrants should not be subsidising applicants without the skills, knowledge or experience to follow publicly available guidance. CropLife also notes that advice given during pre-application assistance is not binding and therefore may fail in its objective to provide certainty to applicants.

- **Application timeframes:** CropLife understands that it is the APVMA's responsibility to meet its statutory timeframes, but where the APVMA does not meet its timeframe for whatever reason the application must be refused, even if the application for registration or approval meets all legislative criteria. 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. The legislative assumption that the APVMA will meet its statutory timeframe 100 per cent of the time for complex applications is unachievable. It is also not acceptable to require an applicant to resort to an Administrative Appeals Tribunal review on an application that is refused purely on the APVMA not meeting its statutory timeframe.

  This unnecessary red tape will lead to reduced certainty, increased investment risk and therefore reduce Australia's attractiveness as an investment destination, further delaying the introduction of more tools to assist in the control of weeds, diseases and pests. Amendments are required to the Agricultural and Veterinary Chemicals Code Regulation 1995 (Regulations) prior to 1 July 2014 to allow sufficient flexibility, when warranted, to extend the timeframe for complex applications to beyond the maximum assessment period.

- **Shut the gate provisions:** CropLife welcomes appropriate measures to streamline the operation of the APVMA's assessments, including restricting the information that the APVMA can take into account when considering an application (Section 8 B & C). Although, the APVMA Regulatory Guidelines are not expected to provide sufficient detailed information on the necessary requirements to provide predictability or certainty in terms of the information requirements to support the full scope of potential applications. CropLife understands that this is due to it being virtually impossible for the APVMA to anticipate the sort of information and data that it may need to adequately assess complex applications, particularly for innovative new products.

  A situation where the APVMA identifies the need for further studies that require the applicant to conduct additional multiple year trials is possible, yet this could not be accomplished within the existing statutory timeframe. As the legislation currently dictates, this situation would require the application to be refused. To this end, it is essential to ensure that the application process has an appropriate level of flexibility to accommodate complex applications.

- **Replace 'hazard' with 'risk':** CropLife is particularly concerned that key concepts around hazard and risk are confused in Section 5A of the Agricultural and Veterinary Chemicals Amendment Act 2013. The hazard is an intrinsic quality of a chemical. The risk represents the likelihood of that hazard occurring. The risk can change with the formulation of a product but the hazard does not. Whilst agreement has previously been reached between CropLife and the Department of Agriculture on what should occur, the construction of the provision is inconsistent with the mutual objective.

- **APVMA consultation with approval holders and registrants:** There has previously been mutual agreement between CropLife and the Department of Agriculture on requiring the APVMA to consult with all approval holders and registrants of a particular chemical product under reconsideration prior to finalising any work plan. CropLife is concerned that there is no legislative requirement for this to occur. These consultation requirements are as important as other consultation processes specified in legislation and should be legislated so registrants and approval holders understand the costs of any proposed work plan.

- **Permits:** Section 112A was amended requiring the APVMA to notify approval holders and registrants relevant to a decision to issue a permit, providing 28 days' notice. CropLife is concerned that registrants need more than just notification of changes to their products. They must have the right to refuse changes in circumstances where they have concerns about the additional use, or are not prepared to assume the risk associated with that use.

- **Limits on use of information:** All data or information that the APVMA requires as part of a new approval or to facilitate ongoing approval/registration is of equal value. CropLife is not aware of any justification for protecting regulatory data submitted as part of a re-consideration for eight years, and other regulatory data for ten. CropLife recommends all regulatory data be protected for ten years, with data submitted as part of a re-consideration being protected for 10 years from date of review decision.

MISSING AMENDMENTS

CropLife has previously suggested a range of reforms that could have been addressed through the *Better Regulation* reform process. While some of these have been considered and addressed during development of the legislation, there remains a set of reforms that CropLife has promoted over several years that have not been included in the package of reforms.

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, if necessary, be more appropriately controlled by another agency. 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 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:** CropLife supports measures to facilitate a more effective reconsideration process. Mechanisms should be introduced 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 incentives to delay decisions to generate additional data.

- **Disbanding the APVMA Advisory Board:** Currently this Board does not have a clear value-add proposition in the formal structure of the APVMA, yet drains APVMA resources through providing sitting fees and secretariat services. Its removal would free those resources to be redirected towards core APVMA functions. If Government and other stakeholders see a value proposition in such a Board, it follows that the costs of supporting its structure should not be funded through the industry cost recovery process. It is important to note that CropLife's views regarding the Board are specific to it as a structural proposition and not a reflection on the current members of the Board whom CropLife views as extraordinarily experienced professionals.

Other reforms may need additional consideration but may ultimately be implemented as part of a concerted effort to improve the efficiency and effectiveness of the Australian regulatory system. Such reforms 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 risk.

- **Implementing a program to actively support minor uses for agricultural chemicals:** CropLife welcomes the Government's commitment to implementing a minor use program and 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 an unintended net adverse environmental consequence. In certain very limited circumstances where the normal assessment processes of the APVMA lead to an extraordinarily and unintended outcome, a mechanism to ensure appropriate decisions would be a useful and proper option. This could be used to authorise some use patterns to ensure the protection of Australian ecosystems.

- **Recognise outcomes of APVMA workplace risk assessments:** New national workplace legislation requires agricultural chemicals to comply with APVMA labelling requirements, as well as Globally Harmonized System of Classification and Labelling of Chemicals (GHS) consistent hazard and precautionary statements. This is an unnecessary increase in red tape and regulatory burden that will cost in excess of $25 million for no discernable improvement in worker safety. Any necessary changes to labels can be accommodated within the existing regulatory framework, not through a second, contradictory approach to labels.

- **Providing for the APVMA to competitively source health and environmental risk assessments:** Currently, these assessments are only conducted by the Department of Environment and the Department of Health, and 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. 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. We would welcome these matters being considered as part of further regulatory efficiency reform.

CONCLUSION

CropLife welcomes the implementation of the Government's election commitment to remove re-approval and re-registration and commends the Department of Agriculture for promptly delivering a quality Exposure Draft.

Agricultural chemicals are a cost effective, efficient and sustainable option for farmers to use to control pests, weeds and diseases and as such represent a core input for modern farming systems. Re-approval and re-registration represent bad policy that would result in increased costs and red tape, while also removing safe and effective products from the Australian market making some production methods and farming businesses unsustainable.

Re-approval and re registration fail to address core problems associated with the current chemical review program and instead, would add additional bureaucracy and inefficiency through ill-considered processes that would have likely resulted in less capacity within the APVMA to deliver timely, high quality chemical reviews. Facilitating improved capability to vary prescribed relevant particulars of approvals or registrations and providing the APVMA the ability to secure information about the safety of chemicals supplied in the market will more effectively ensure the APVMA's record of approved products is consistent with that currently being produced.

Reductions in red tape by providing for less frequent registration renewals of agricultural chemical products and allowing the APVMA to administer the Australian agricultural chemical portfolio in accordance with Australia's specific circumstances will improve the efficiency and effectiveness of the Authority.

CropLife is therefore confident that the Exposure Draft, *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2013* will assist in creating a streamlined, effective regulator that is capable of delivering more timely risk assessments, approvals and registrations. CropLife remains eager to assist the Government deliver further previously suggested reforms to ensure this outcome is realised.