Representing the Plant Science Industry

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17 April 2014

Committee Secretary
Senate Standing Committees on Rural and Regional Affairs and Transport
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Secretary

On behalf of CropLife Australia (CropLife), I provide the attached submission to the Senate Standing Committees on Rural and Regional Affairs and Transport Inquiry into the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014.*

CropLife has always advocated for a world class, scientifically and technically competent, independent and efficient regulator that ensures the highest levels of protection for human health and environmental safety, to facilitate the farm sector's access to these crucial products for agricultural production. It is on this basis that CropLife supported the majority of the reforms introduced and passed by the Federal Parliament last year. CropLife, however, remained deeply concerned that the re-registration and re-approval measures increased the regulatory burden on applicants, approval holders and registrants while not delivering any outcomes resulting in public policy improvements.

It is also on this basis that CropLife supports this Bill to ensure that the regulatory reform and modernisation that has been achieved is not undermined by unnecessary and costly regulation that does not provide any meaningful benefit and may, in the medium to long-term undermine the regulator's focus on the protection of human health and the environment.

CropLife supports this Bill noting further reforms as detailed in previous submissions are required to reduce unnecessary red tape and improve the efficiency and effectiveness of the Australian Pesticides and Veterinary Medicines Authority through the removal of excessive, inappropriate and ineffective regulation.

Please do not hesitate to contact me or CropLife's Policy Manager for Agchem Regulation and Stewardship, Mr Alastair James, should you require clarification in respect of any aspect of this submission.

Yours sincerely

Matthew Cossey
Chief Executive Officer

Attach:

Representing the Plant Science Industry

CropLife AUSTRALIA

SUBMISSION TO

THE SENATE STANDING COMMITTEES ON RURAL AND REGIONAL AFFAIRS AND TRANSPORT

INQUIRY INTO "*THE AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (REMOVING RE-APPROVAL AND RE-REGISTRATION) BILL 2014*"

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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 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 are global leaders in their full lifecycle approach to industry stewardship and contribute 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 ethical and responsible practices from discovery and development of crop protection products through to their use, and the final disposal of 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 to ensure they present no unacceptable risk to users, consumers and the environment. In 1995, it took the assessment of 52,500 compounds to develop one new effective crop protection chemical active. It now requires the assessment of more than 140,000 compounds and expenditure of more than $250 million (US) over a 10 year period to bring just one new successful crop protection product 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.

The plant science industry itself is the strongest advocate of the regulatory system and the need to maintain the primacy of protecting human health and the environment. Crop protection products must be used sparingly, carefully, responsibly and strictly in line with their registered label instructions. 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. An efficient and technically proficient regulator is crucial to the farming sector, so that Australian farmers have access to the most efficient technologies and 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. No cost benefit analysis or any other evidence has been presented before or since the original introduction of these measures to demonstrate that this reform would deliver any net benefit. 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;
- 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; and
- The over-burdening of the regulator in administrative processes rather than a focus on ensuring human health and safety outcomes.

Crop protection products are crucial to modern integrated pest management techniques and systems used by farmers. 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]. The environmental impacts of an overburdened regulator that is tasked with arbitrary, time-based reviews will also undermine land management and conservation practices such as the proper management of invasive species in the mid- to long-term.

Further, the responsible use of agricultural chemicals generates direct benefits for consumers. According to a Deloitte Access Economics report released 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. This view is supported by the broad range of grower and farmer groups as well as the majority of state governments.

[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.

The existing APVMA Chemical Review Program

Re-approval and re-registration represents poor 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 both confirmed that the APVMA has reasonable arrangements in place for identifying and prioritising existing chemicals requiring review[2].

The APVMA's existing Chemical Review Program has been effectively designed to meet the policy objective of ensuring human and environmental health. Limited resources are dedicated to assessing new risks, or existing risks as they are identified, rather than spreading those resources across all chemicals, even where there is very low risk. This risk based assessment is world's best practise because it allows thorough and prompt focus on emerging risks.

The strengths of the current legislation are as follows:

- Rigorous pre-market assessment;
- Targeted, reconsideration scheme (chemical review) where a potential new risk can be assessed and prompt action taken;
- A positive obligation where registrants must provide new data where they become aware of it (s161); and
- A system where the APVMA actively seeks out new information in collaboration with overseas regulators, and where anyone can supply new information if they wish.

Criticism of the Chemical Review Program stems from the timeliness of the review process, not its scientific and technical assessment competence. This is a criticism CropLife Australia has also made over several years, however, the plant science industry has always recognised that improvements only needed to be generated at a regulatory management level, not through the introduction of extra bureaucracy. The additional legislation and bureaucratic processes resulting from re-approval and re-registration would only further slow the process and make it less effective. Whereas, the amendments to the Agricultural and Veterinary Chemicals Code Regulations 1995 introduced on 1 July 2013, specifically section 78B, introduced a formula that determines the maximum period the APVMA must conclude reconsideration (chemical review). This will result in more timely reconsiderations, with the maximum reconsideration timeframe now being 52 months.

The APVMA Chemical Review Program has also been strengthened by recently introduced amendments that significantly improve the APVMA's compliance tools. 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. This includes information from holders of active constituent approvals or permits who are obliged under the legislation to provide any relevant information on an active constituent or product to the APVMA as soon as they become aware of it. There is a statutory, positive obligation for all companies to provide any and all new data.

Re-approval and re-registration has the potential to diminish the effectiveness of the targeted, intuitive, proactive risk based chemical review program already established in Australia. It poses a real risk in the medium to long term of undermining the regulator's focus of protecting human health and environmental outcomes in the registration system.

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

International best practice

The existing APVMA Chemical Review Program accords with international best practice as dictated by the Organisation for Economic Co-Operation and Development's Regulatory Policy Committee's recommendation on regulatory policy and governance[3]. The two points from this document that are key to Australia's Agricultural and Veterinary Chemical regulations are as follows:

- At point 4: "Clearly identify policy goals, and evaluate if regulation is necessary and how it can be most effective and efficient in achieving those goals. Consider means other than regulation and identify the trade-offs of the different approaches analysed to identify the best approach"; and
- At point 9: "As appropriate apply risk assessment, risk management, and risk communication strategies to the design and implementation of regulations to ensure that regulation is targeted and effective. Regulators should assess how regulations will be given effect and should design responsive implementation and enforcement strategies."

It cannot be argued that the addition of re-approval and re-registration can improve on this system. What can be argued is that poorly considered and excessive regulation will undermine the existing system, increase production costs, discourage investment and innovation and deliver poorer safety, health and environmental outcomes.

'Grandfathered' chemicals

The concern that agricultural chemical products have been 'grandfathered' onto the National Registration Scheme in 1996 without assessment is false. Prior to the formation of the APVMA, responsibility for the approval and clearance of active constituents originally resided with the Technical Committee on Agricultural Chemicals (TCAC) and then from 1 July 1989, with the Australian Agricultural and Veterinary Chemicals Council (AAVCC).

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

Furthermore, the registration of any new substantial use patterns, formulations or application technique for chemical products containing approved active constituents, including all products that were transferred from the state based systems to the national system, triggers the reassessment of supporting environmental and human health data or the generation of new data.

Economics

The APVMA estimates show that cost recovery would need to increase by nearly $2 million in 2015-16 to manage the additional administrative burden of re-approval and re-registration[4]

Based on analysis conducted by CropLife Australia in 2011, direct costs to registrants are conservatively expected to be at least $6.75 million per annum, representing an approximate increase of 25 per cent in total cost recovered fees imposed on registrants[5]. A more likely outcome would be in excess of $10 million per annum.

The opportunity costs from registrants supporting existing registrations rather than innovating, developing and registering new, safer and softer agricultural chemical products will be significant. Australia's farmers will be denied access to the chemical tools that they need to meet ongoing sustainability and productivity challenges

Further, as this increase in cost is passed down the chemical supply chain, distributors and retailers will need to increase their prices by more than the actual increase in price to maintain an adequate margin for the product. As a result, the actual cost to farmers will be greater than the $6.75 million estimate.

3 http://www.oecd.org/gov/regulatory-policy/49990817.pdf

4 http://www.apvma.gov.au/about/work/docs/apvma_cris_2013-15.pdf

5 http://www.croplifeaustralia.org.au/wp-content/uploads/2011/02/CropLife-Better-Regulation-Costs-Supp-Sub-Final.pdf

European Union example

The current agricultural and veterinary chemical re-registration system in the European Union (EU) is based on Regulation 1107/2009. The regulators have been overwhelmed by trying to meet the arbitrary timeframes and many EU members are now in support of a simpler system as they do not have the resources to make the system work. In most cases, the re-evaluations are not completed in time, creating significant administrative burden in extending the deadlines to allow the completions of the reviews.

Re-approval and re-registration in Australia would mean spreading the same, limited resources over the assessment of all chemicals, regardless of risk, rather than focusing those resources on the risk based identification and prioritisation of chemicals requiring review. It has the real and genuine potential to undermine the regulator's ability of ensuring the highest levels of human health and environmental protection.

Re-approval and re-registration in Australia would turn the APVMA from a health and safety regulator to a bureaucratic administrator.

CropLife continues to support the existing approach to identifying and prioritising chemicals for review. 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

The APVMA should be free to administer the Australian agricultural chemical portfolio in accordance with Australia's specific circumstances to ensure the primacy of protecting human health and the environment for the Australian community.

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. Therefore, the introduction of an 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 is arbitrary, unwarranted bureaucratic red tape.

RENEWAL OF REGISTRATIONS

Renewal of registrations is purely an administrative process. Reducing red tape by allowing for less frequent registration renewals of agricultural chemical products will streamline the APVMA's administrative workload enabling it to focus on its core business of registering chemical products whilst ensuring human health, safety and environmental protection. 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

Measures that facilitate approval holders and registrants applying to the APVMA to vary prescribed relevant particulars of their approval or registration will, in some circumstances, 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 inhibit 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.

CONCLUSION

CropLife welcomes the implementation of the Government's election commitment to remove re-approval and re-registration. The passage and implementation of the initiatives in the Bill would ensure a more streamlined regulatory system and a more effective regulatory authority that would in turn effectively protect human health and the environment.

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 poor public policy that would not deliver any improvement in the protection of human health or the environment, but would result in increased costs and red tape, while also causing the loss of 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 *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 201r* will assist in creating a streamlined, effective regulator that is capable of delivering more timely risk assessments, approvals and registrations.