18 April 2014

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

Dear Secretary

Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014

Thank you for the opportunity to make a submission to the Senate inquiry into this Bill. The Plastics and Chemicals Industries Association (PACIA) is the peak national body representing the business of chemistry in Australia. Our members include chemicals manufacturers, importers and distributors, logistics and supply chain partners, raw materials suppliers, plastics fabricators and compounders, chemicals and plastics recyclers and service providers to the sector. These businesses range from small, family owned companies and medium sized enterprises to leading national and multi-national companies. Many of our members are both registrants and approval holders under the Agricultural and Veterinary Chemicals Code.

The chemicals and plastics industries provide essential materials and inputs to many other sectors including automotive, aerospace, defence, healthcare and pharmaceuticals, consumer products and cosmetics, water industry and treatment, food products, mining and resources, building and infrastructure, education and information technology, packaging, construction and consumer appliances.

Balanced, consistent and effective regulation is essential to supporting an innovative, vibrant, productive and sustainable chemicals industry in Australia. To this end, PACIA supports appropriate measures that effectively balance the need to ensure that agricultural and veterinary chemicals present no unacceptable health, safety or environmental risks with the need to ensure that the legislative scheme facilitates the introduction of newer safer and softer products, chemistries and technologies.

Sincerely

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Background/Introduction

Prior to 2010, various industry groups had for many years expressed concern that the APVMA's processes and procedures were imposing a significant barrier to the introduction of newer, safer and softer technologies. This resulted in some Australian farmers being denied access to some products and uses available in our key competitor producers. The high cost of complying with Australia's regulatory scheme to approve and register new active constituents and products was considered to be a key impediment to introducing new technologies and products.

Amendments to the Agricultural and Veterinary Chemicals Code introduced in 2013 were designed to achieve two objectives:

- Improve the efficiency of the APVMA with appropriate reforms to modernise the regulatory system for agricultural and veterinary system, and
- Improve the effectiveness of the system by introducing a new 're-registration and re-approval' scheme to address perceived gaps in the management of agricultural and veterinary chemicals.

A strong, credible and effective regulator for agricultural chemicals and veterinary medicines is essential to maintain community confidence in the system for controlling health, safety and environmental risks. However, an overly conservative and unbalanced regulatory regime may result in reforms that discourage new technologies and innovations, potentially leaving Australian farmers without the safest, newest and most effective tools that they need to compete in a global market. Where regulatory burdens become so great that they discourage the introduction of newer, safer and softer technologies, the Agricultural and Veterinary Chemicals Code may in fact result in perverse outcomes by forcing farmers to rely on older chemistries and technologies.

1. Removing re-approval and re-registration

PACIA supports the removal of the re-approval and re-registration scheme. This position is informed by two key observations:

- Re-approval and re-registration substantially duplicate other provisions of the Agricultural and Veterinary Chemicals Code, and
- The scheme will impose potentially significant costs on approval holders and registrants that are not well targeted to areas of greatest risk.

The APVMA already has significant powers to vary, recall, suspend, cancel or review existing approvals and registrations. These powers can be exercised at any time whenever the APVMA believes that there to be an uncontrolled or excessive risk from the use of the product. Retaining these powers provides the APVMA with sufficient authority to comprehensively address any potential risk as soon as the APVMA identifies it.

With limited resources, introduction of significant, new regulatory processes runs the risk of directing scrutiny away from active constituents in need of review in favour of administrative 'busy work' to re-approve and re-register products that have a long history of safe and effective use and no identified concern regarding their safety.

Indeed, the inception of the re-approval and re-registration intended the scheme to be risk-based, however its implementation, by failing to identify areas of risk being targeted has resulted in a scheme that is not targeted at risk, in contrast to the rest of the regulatory scheme.

Support for the re-approval and re-registration scheme has generally been based on misunderstandings of chemical markets, company practices and risk management approaches adopted in Australia. Support for re-registration and re-approval has been based on perceptions that:

- Australia allows farmers to use chemical products that have been 'banned' in overseas markets. This claim fails to recognise that each market has unique requirements for agricultural and veterinary chemicals dependent upon crops produced, pest pressures, environmental

circumstances and market requirements. Indeed, the presence or absence of a particular chemical in a market is largely driven by the commercial decisions of an approval holder or registrant.

Indeed, Australia has not registered many chemicals available in other markets, but that does not mean that they have been 'banned' in Australia.

However, if a particular use of a chemical or product might present an unacceptable risk, then the APVMA may vary, recall, suspend, cancel or review that particular chemical or use. The APVMA has always had the capacity to make appropriate management decisions, and monitors international developments and new data to consider implications for Australian approvals.

- Australia relies on chemicals that have not been subject to modern assessments – some for more than 40 years. This claim ignores the review of all grandfathered chemicals that occurred prior to the establishment of the National Registration Scheme. In the early 1990s, the Australian Agricultural and Veterinary Chemicals Council undertook a wide ranging process to review all of the active constituents approved in Australia and reaffirmed that these active constituents continued to meet necessary safety standards.

Ultimately, where new risks are identified – from any chemical product, whether new or old, the APVMA will retain sufficient power to promptly and proactively manage that risk. Re-registration remains a policy solution in search of an identifiable problem. Without identifying a clear problem that re-registration or re-approval can address more efficiently than existing measures, the policy response can be removed without any detrimental impact on health safety or environmental outcomes.

2. Reducing red tape by allowing for less frequent renewal of registrations

PACIA welcomes measures to reduce red-tape by allowing for less frequent renewal of registrations. Allowing registrants to renew products for one year represents and useful reduction in red tape. PACIA supports flexible renewal options.

3. Addressing concerns with chemical product quality.

PACIA supports appropriate monitoring, compliance and enforcement powers to allow the APVMA to obtain the information it needs to ensure that only products that comply with legislative requirements are supplied to the Australian market.

Ensuring that high quality, safe and effective products are supplied to the Australian market is an essential component of the agricultural and veterinary chemical regulatory scheme. This requires a comprehensive, targeted and risk based compliance and enforcement program that seeks to identify those products with the highest potential risk to health, safety and environment. Such a program must focus on products and introducers that seek to avoid regulatory scrutiny and registration rather than focussing on technical compliance issues by registrants that have little or no impact on product safety.

4. Simpler variations to approvals and registrations

PACIA notes that some stakeholders have previously expressed concerns that products supplied to the Australian market may not match the specification supplied to the APVMA at the time of registration. This may occur for a number of reasons that have no impact on product quality or safety – such as supplier changes or new, more advanced manufacturing processes. However, such specification drift can complicate the APVMA's compliance activities in circumstances where a product has 'drifted' from its initial specification.

A rigorous regulatory scheme must be underpinned by a robust compliance scheme to provide community confidence that health, safety and environmental protections are being maintained. Hence, it is important for registrants to have access to simple, low cost processes to update product specifications from time to time.

While the content of the legislative instrument to be made under section 26A would need to be subject to additional consultation to ensure that it encompasses the greatest range of potential variations possible without undermining product safety, PACIA supports this initiative as an important component that, coupled with appropriately targeted compliance activities, can successfully and efficiently address concerns about products supplied to the Australian market.

PACIA looks forward to working with the APVMA and the Department of Agriculture to identify those variations to product specification that can be notified under a s26A legislative instrument.

5. Reducing red tape by no longer requiring annual returns about active constituents

PACIA supports amendments to remove the obligation for companies to annually report the import, export or manufacture of 'technical grade' active constituents. These reporting obligations are not necessary for the APVMA to conduct its risk management activities and can safely be removed without any impact on health, safety and environmental outcomes.

6. Improving efficiency by requiring electronic lodgement of information and fees

Electronic lodgement can improve efficiency by minimising the handling of documents by the regulator. Provided that electronic lodgement reduces costs, PACIA supports this reform. Wherever possible and simple to do so, the APVMA should investigate the potential for efficiency from electronic lodgement.

7. Obliging access to information about chemicals that the APVMA holds

PACIA understands the challenges that a dynamic commercial environment place on companies managing their chemical portfolios. As some products have very long product lifespans, they may exist through a number of commercial restructures, divestments and mergers. From time to time this may mean that a company is not fully aware of the information that the APVMA holds in relation to its registered products. This places particular challenges on the APVMA's compliance activities and on registrants' responsibility to manage their product portfolio.

Currently, PACIA understands that some registrants have used the freedom of information process to access information about their registered products. This may represent an inefficient mechanism for registrants to access relevant information from the APVMA. Better processes to improve the communication between the APVMA and registrants, and to make information that the APVMA holds available to registrants is supported.

PACIA would welcome further discussions on appropriate fees payable to the APVMA where a registrant request information from the regulator. However, PACIA would expect that there would be mechanisms to enable access to documents efficiently and at low cost.

8. Other amendments consequential to existing reforms

PACIA supports the consequential amendments, particularly to reinstate the 2010 amendments to allow the APVMA to amend the FSANZ Maximum Residue Limit standard.