

## **File Note**

### **Submission on the operation of amendments to legislation made by the Agricultural and Veterinary Chemicals Legislation Amendment Act 2013.**

Our company as part of the business structure has significant involvement with the operations of the Australian Pesticides and Veterinary Medicines Authority (APVMA). As such any operation issues associated with the performance of the APVMA can and does have significant impact on both the financial position of our company and the operation efficiencies within the business structure.

We currently holds ~161 registrations with the APVMA for agricultural chemicals or active ingredients, with a further 11 applications currently under evaluation. We invest heavily in the development and marketing of new products along with education training for the end users. This investment and planning is only achievable when the business can operate efficiently on the basis that the regulatory timeframes set forth by the APVMA are maintained.

Most agricultural chemicals used in Australia have a narrow seasonal application window, typically less the 8 weeks of the year nationally. This additional pressure on timing requires the company to plan months in advance if they intend to successfully market, which is not achievable until registration is attained, hence a large dependence on the regulatory timeframes being met. Recent analysis by the business has determined that in order to successfully enter the market for a new product, the business need to be certain that the application is going to be approved between 6 – 9 prior to the narrow two month sales window. As part of the business planning. This nine month lead time is calculated into the planning process, with additional two months' buffer time to allow for lag on the regulatory time frame.

Recent examples with the APVMA surrounding both the inability for them to meet the regulatory timeframes set forth as part of the amendment has continued to demonstrate this along with poor communication surrounding such matters.

#### **Current Examples**

Currently we are still trying to gain approval for an application with was due in October 2018, allowing sufficient time to supply during the 2019 fungicide season which occurs typically between mid-July and mid-September. This application is now currently over 5 months past the due date of 20<sup>th</sup> of October 2018. The APVMA has made no formal request for further information, nor has the timeframe been extended. The regulatory timeframe was only set forth as 9 months for this application. For this product in particular we have now missed the opportunity to successfully market the product and will have to wait until 2020 until having the opportunity again.

Similar issues have been observed with other applications over the last few years, including a missed opportunity to market another product over the 2018/19 summer due to poor communication on the changes to the timeline. We were formally advised there would be a three-month extension to the regulatory timeframe on the 22<sup>nd</sup> of August, which was only provided days before the initial due date of 16<sup>th</sup> September. The application was then approved

25<sup>th</sup> September 2018, which if we had not been informed of a new due date of 16<sup>th</sup> January 2019 on the 21<sup>st</sup> of August 2018

Our company unfortunately has formed the belief that in an effort to improve the quarterly performance statistics, for which the October – December 2018 quarter was only publically published on March 8<sup>th</sup> 2019. The APVMA has made a decision that once an application is past due date they will work on other applications still within the regulatory time frame in order to have as many applications approved within the regulatory timeframe as possible. It is with this belief that once the due date is past and an application is yet to move into finalization, then the communication on said application beaks down. This adds further difficulty in the business trying to make a commercial decision on supplying a product. To the best of our knowledge there is no statistic kept on how long past due applications go on average, anything past due by as little as 1 week is treated the same as applications which fall many months overdue.

Further on the issues with communication is the continual changing of the companies contact person / case manager. Since November 2018 we are now dealing with our 4<sup>th</sup> Case Manager. This appears to be adding further time to some applications as we are having to continual repeat communications. Failure of the APVMA to update the portal, which is meant to act as the businesses go to section for up to date information on applications, is leaving the business with no other option than to continually email our ever changing case manager for updates on progress which in inefficient for both parties.

As a significant levy payer contributing approximately \$x per annum to the APVMA by ways of product fees, and further to that, and additional \$40,000 – \$75,000 in general application fees. It is of the belief that this level of communication and consistency isn't acceptable when the organisation is funded directly by stakeholders, who's business's are penalised by the APVMA being unable to meet and conform to their own regulator timeframes and regulations.