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Agvet Chemicals Regulation Reform, M.6.137  
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### **Submission on the Exposure Draft Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2013**

The Australian Forest Products Association (AFPA) welcomes the opportunity to provide comment on the Exposure Draft Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2013 (Bill).

AFPA is the peak national body for Australia's forest, wood and paper products industry. We represent the industry's interests to governments, the general public and other stakeholders on matters relating to the sustainable development and use of Australia's forest, wood and paper products. Our industry makes a significant contribution to the Australian economy especially in rural regions.

AFPA members include native forest managers, plantation growers, and wood and paper product manufacturers. These industries use relatively small amounts of agricultural and veterinary (agvet) chemicals when compared with other larger agricultural sectors.

However, chemical use is critical to maintaining and improving the industry's productivity and competitiveness to meet Australia's wood fibre and product needs into the future. As such, AFPA has a strong interest in agvet chemical regulation reform. In principle, AFPA supports reform processes that remove red-tape by improving the efficiency of regulation and regulatory bodies, and create more certainty for all stages of the agvet assessment and registration process.

AFPA's submission builds on our earlier submissions on previous reform resulting in the *Agvet Chemicals Legislation Amendment Act 2013 (2013 Act)* and subsequent parliamentary committee considerations. This submission provides comment on the key issues addressed in the Bill and highlights important additional areas of reform that are needed.

## Previous industry concerns regarding the previous reform that resulted in the 2013 Act

AFPA, and other stakeholders (representing a broad cross-section of other chemical end-user industries) detailed on multiple occasions significant concerns regarding the previous reform that resulted in the 2013 Act including:

- *The lack of any real reform and regulation simplification.* The 2013 Act appeared to increase the amount of red tape, process and cost recovery (fees), with very little in the way of increasing efficiencies and certainty;
- *The proposed re-approval and re-registration process* would have increased costs and uncertainty for industry, making it very difficult to maintain the existing suite of chemicals and minor uses that our industry relies on;
- *The proposed risk assessment process.* There remains continued uncertainty in the detail and application by the regulator of the proposed risk assessment framework underlying the approval process. This framework and the selection of re-approval and re-registration periods, needs to be better aligned with the principles of assessment for 'risk' rather than 'hazard'; and
- *The issue of minor use.* Due to the forest industry's relatively small chemical use, the continued availability of minor use permits coupled with an effective and streamlined minor use permit approval process, is essential to ensure chemicals are available to use for forestry applications. The 2013 Act did not include an appropriate framework for dealing with the issue of minor use.

Overall, the 2013 Act was a poor outcome for the forest, wood and paper product industries, as it introduced additional tests, hurdles and regulation that did not provide any clear benefit to agvet chemical registrants, users or the community. The 2013 Act is likely to increase the cost burden, increase complexity, create unnecessary barriers, duplicate existing processes, and be inefficient. It creates significant uncertainty for a chemical end-user, such as the forest, wood and paper product industries, around the continued availability of operationally cost effective and innovative chemical solutions into the future.

## Government Agvet Chemical Regulation Reform Commitments

AFPA appreciates the Government's stated commitment to:

- *'reforms that further improve the efficiency of agvet chemicals regulation. Specifically, to remove re-registration and work with industry to implement further improvements through legislation and administrative change'; and that the*
- *'existing chemical review mechanisms allowed the examination of newly discovered risks about the safety, efficacy or trade impact of a chemical, so new mechanisms that duplicate the existing system and impose additional costs industry are not required'; and also highlighted*

- *'further reforms that will include efficiencies that free up APVMA resources to allow fast tracking of registrations and reviews of existing registrations; introduce contestability for APVMA assessments; improve use of overseas experience with chemicals; and improve access to chemicals for specialty crops and minor uses.'*

If effectively implemented these reforms could remove significant red-tape, increase efficiency and certainty, and decrease industry's cost burden and regulatory complexity.

### **AFPA's comments on the key issues detailed in the Bill**

AFPA's comments on the key issues that the Bill seeks to address, include:

- *Removing re-approval and re-registration*  
AFPA supports amendments to remove the mandatory re-approval and re-registration provisions introduced by the 2013 Act. The mandatory re-approval and re-registration provisions were unnecessary and did not meet the often stated objective to *'increase the scrutiny of chemical constituents and products through a scheme that minimises impacts on industry'*. The additional regulatory processes were likely to increase costs and uncertainty for industry, making it very difficult to maintain the existing suite of chemicals and minor uses. AFPA also notes that the Australian Pesticides and Veterinary Medicines Authority (APVMA) still retains a re-consideration process of registered chemicals based on an ongoing process of assessment of human health or environmental risks.
- *Reducing red-tape by allowing for less frequent renewal of registration*  
AFPA supports amendments to allow for less frequent renewal of registration. In relation to the frequency of renewals, a potential model could be where the reasonably assessed risk of the chemical is higher, the shorter the frequency of renewal of registration (for example an assessed high-risk chemical could have a one (1) year renewal and longer intervals for lower-risk chemicals).
- *Addressing concerns with chemical product quality.*  
AFPA understands the Government's policy objective for the APVMA to improve its ability to secure information about the safety of chemicals supplied in the market. AFPA urges that any reform in this area be scientifically based, targeted at areas of concern, and aligned with the principles of assessment for 'risk' rather than 'hazard'. AFPA supports the implementation of an effective and practical safeguard system to be applied to the APVMA in relation to this issue. The safeguard system would prevent the APVMA from requiring information unless it believes it is reasonably necessary to protect human, animal, plant or environmental health or safety, or implications on trade.

- *Reducing red-tape by allowing for simpler variations to approvals and registrations*  
AFPA supports ‘in principle’ this amendment as it aims to provide efficient regulation and is underpinned by the principles of assessment for ‘risk’ rather than ‘hazard’. The proposed approach detailed is also supported (i.e. ‘APVMA is prevented from setting out the variation unless it has considered whether it would be safe or would not affect efficacy or trade’).
- *Allowing for more efficient access to information about chemicals that the APVMA holds.*  
AFPA supports reform that allows improved and more efficient access to information held by APVMA to persons eligible to receive it. Although significant caution is still needed around any information deemed confidential. AFPA would also endorse a measured push towards streamlining electronic lodgement of application forms, information and data, coupled with the flexibility of an exemption for those applicants with a genuine need.

### Further reform areas of agvet chemical regulation

The Bill details some positive reforms that will improve the existing regulation and regulatory bodies, and create more certainty for all stages of the agvet assessment and registration process. However, AFPA proposes that there are still significant further reform areas of agvet chemical regulation that will need to be addressed.

These include:

- *Proposals on risk assessment process.*  
There remains continued uncertainty in the detail and application by the regulator of the proposed risk assessment framework underlying the approval process. This framework needs to be both scientifically based and aligned with the principles of assessment for ‘risk’ rather than ‘hazard’. Further reform in this area is needed.
- *Minor use.*  
Due to the forest industry’s relatively small chemical use, the continued availability of minor use permits coupled with an effective and streamlined minor use permit approval process, is essential to ensure chemicals are available to use for forestry applications. Further reform and red-tape reduction is needed to ensure that minor uses are equitably considered in the regulatory framework.

- *Continue improvement of cost recovery, assessment, approval and registration processes by the Regulator.*

Another important issue not fully addressed by the Bill is the current process of application and registration of chemicals through the APVMA regulatory process, and the associated cost and time incurred by applicants to undertake these processes. It is understood that applications for product registration by APVMA involve many processes, but in general applications are processed via a system that requires applicants to provide significant amounts of detail on the particular chemistry, manufacture, efficacy etc. These applications are very detailed and applicants take many months to prepare and submit them.

While acknowledging the need for relevant data and information as part of the chemical registration process, it is apparent is that some of the timeframes for assessment are too long. There is concern about the capacity of the regulator to deal with applications in a timely manner. There may be potential scope for applicants to have access to provisions for a 'pay for priority' system in order to obtain prioritised and timely assessment, especially related to the level of assessed risk of the chemical. Further reform to provide flexibility and reduce red-tape and cost is needed.

The forest, wood and paper products industry supports the Government's efforts to effectively and efficiently reform chemical regulation and we urge the Government to continue the reform process to address the remaining outstanding issues in agvet chemical regulation.

AFPA is committed to working with the Australian Government and other stakeholders on its development and implementation.