Submission to the Agriculture and Veterinary Chemicals Legislation Amendment Bill 2011

February 2012

The Victorian Farmers Federation

The Victorian Farmers Federation is Australia's largest state farmer organisation, and the only recognised, consistent voice on issues affecting rural Victoria.

The VFF consists of an elected Board of Directors, a member representative General Council to set policy and eight commodity groups representing dairy, grains, livestock, horticulture, chicken meat, pigs, flowers and egg industries.

Farmers are elected by their peers to direct each of the commodity groups and are supported by Melbourne-based staff.

Each VFF member is represented locally by one of the 230 VFF branches across the state and through their commodity representatives at local, district, state and national levels. The VFF also represents farmers' views on hundreds of industry and government forums.

Andrew Broad
President

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Executive Summary

The Victorian Farmers Federation (VFF) supports reforms that deliver more effective and efficient agricultural and veterinary chemical regulation. However the Federal Government's draft Agricultural and Veterinary Chemical Regulation Bill falls well short of the mark on achieving these goals.

The draft bill will increase regulatory costs and potentially reduce the availability of chemicals crucial to Australia's food producers. The major flaw in the bill is its imposition of a mandatory re-registration process for all chemicals, every seven to 15 years (Schedule 2). The merits cited for this change are it will align Australia with similar US and EU standards, but this argument fails to recognise the high cost of re-registration on a much smaller Australian market.

The risk is multinational agri-chemical companies will withdraw crucial products from Australia, rather than invest in re-registration. CropLife Australia estimates the cost of re-registration at $100,000 to $500,000 (Source: Better Regulation of Agricultural and Veterinary Chemicals RIS November 2011).

The VFF calls on the Federal Government to abandon the mandatory re-registration proposal from the bill and simply retain the current triggers for chemical reviews – health and environmental concerns. Creating mandatory timeframes for re-registration will not deliver benefits to the community and crucially does not address the fundamental flaws in the current system, which lead to major delays in processing registrations and permits.

VFF is also concerned the data protection provisions could be exploited by some agri-chemical companies to restrict rivals from the use of key active substances to manufacture generics, under a mandatory re-registration process. This has potential to remove generic label chemicals from the market and increase the cost of chemicals of those that remain.

The VFF is supportive of the bill's proposals (Schedule 3) to boost the efficiency of the registration process by:

- Allowing the APVMA to refuse inferior or deficient applications.
- The use of electronic application forms.
- the use of overseas data, where applicable, to avoid unnecessary expensive duplication of work that has already been done to an acceptable standard and considered in the context of, or validated by research of Australian use practices and applications.

The VFF supports the 'Shut the gate' provisions of the bill to ensure swift completion of chemical re-registrations. However we request permit applicants not be exposed to the same provisions, simply due to their lack of understanding of the regulatory and application process.
The VFF believes the APVMA still needs to guide and assistance to applicants seeking emergency, research or minor use permits.

The VFF is concerned assistance will now only be available at a cost to farmers seeking to gain a permit. This will add significantly to the input costs affecting already minimal returns.

While opposing mandatory re-registration the VFF wants to see improvements in the current system of reviewing chemicals to ensure they are based in a scientific manner and Australian conditions. Before suspending any chemical the APVMA must fully investigate whether industry can utilise risk management practices to address any concerns. The use of chemicals varies across Australia's many farming zones, let alone those of European conditions for example, and to impose a "one size fits all" regulatory measures is not appropriate.

The VFF also wishes to highlight its on-going concern at the under-resourcing of the APVMA. We note the Federal Government has allocated just $8.75 million to implement the reforms outlined in the draft bill, which appears to be grossly inadequate. The new mandatory re-registration requirements will significantly increase the workload of an already over-burdened regulator.

Rather than the Bill achieving its objective to increase efficiency and effectiveness, the increased burden on the regulator will in reality then be 'pushed-back' to the market registrants resulting in increased costs to farmers and in effect market failure.

In summary, the VFF's concerns are that the increased regulatory burden created by this bill will:

- Increase costs to farmers;
- Create inefficiency in an already overburdened regulatory system
- Impose new costs which deter companies from re-registering chemicals, leading to the loss of valuable farm chemicals in Australia;

As a result of these concerns the VFF suggest the following amendments to the regulation:

1. **Abandon mandatory re-registration and retain the current triggers for chemical reviews – health and environmental concerns;**
2. **Implement the 'Shut the gate' provisions of future chemical reviews to ensure swift completion of chemical re-registrations. However permit applications should still be given assistance;**
3. **Review the impact of the bill once enacted.**

General Comments on the Draft Bill

The VFF is concerned that the bill will not deliver the desired outcomes of quality regulatory reform. The goal of regulatory reform should be to reduce needless red tape and improve industry performance. The mandatory re-registration of chemicals every 7 to 15 years will not deliver on either of those goals. There is the potential this reform will increase the regulatory burden on chemicals, impacting the chemical availability for the food producing community.

Farmers are concerned big chemical companies will no longer support out of patent actives allowing the companies to sell new patented chemicals at a significantly higher cost to the end user.

Those important agricultural production chemicals referred to as 'Minor Use' or 'speciality crop' chemicals, will simply not be re-registered if chemical companies cannot justify the expenditure to undertake the required regulatory research.

There is also potential that Data Protection provisions imposed on the market could result in existing registered chemicals available for "generic" brand production, being re-registered and captured by the Data Protection provisions. This has potential to remove generic label chemicals from the market and certainly increase the cost of chemicals the market and to Australian producers.

The VFF has the following specific comments in relation to the draft bill's schedules.

Specific Comments on the Bill

Schedule 1 – Decision making using a risk-based framework

The VFF supports the development of a risk-based framework, including a volume setting out the principles and a more detailed volume setting out processes. These framework documents will dispel some of the current confusion particularly around some processes.

We support the flexibility on the requirement for trade assessments however the framework needs to clearly set out how and when trade assessments are required. This will provide certainty for trade exposed industries, or those industries who supply trade exposed industries. For example the cattle industry needs certainty that chemicals used by the grains and fodder industries do not affect its access to key markets. Also, it is worth noting it is not just producers that require this certainty, overseas markets expect that we have robust systems to manage residue risk. However we must ensure, that for markets that are not trade affected, we do not impose unnecessary additional cost on registrants that will ultimately be passed on to farmers.

The VFF supports efficacy as a mandatory assessment. Farmers need certainty that the products purchased will provide the benefits outlined and ensure that farm risk assessments are not compromised by the ineffective use of chemicals. We are concerned that a removal or loosening of efficacy requirements could put product users (farmers) into the role of having to verify that a product is fit for purpose. This would also see them having to rely on the Competition and Consumer Act 2010, after the fact, for any potential remedies in situations where this is found not to be the case. Buyer beware principals should not apply when managing risk.

Schedule 2 – Continuation of approvals and registrations

Deregistration should only be considered on a risk-based approach. Mandatory re-registration must not be adopted and is a simplistic approach to ensuring public confidence in the regulatory process. The costs associated with re-registering a product, when no scientific fact based evidence has been presented to support a concern, will flow back to farmers or result in the loss of crucial chemicals.

Item 4 and 5

The VFF supports the assurance the APVMA will notify FSANZ about any continuation application that may require an amendment to Maximum Residue Limits (MRLs).

Item 12

The VFF also believes there is no scientific evidence to show the current system is not working and any amendments will lead to higher costs to farmers.

The amendment provides for approvals to expire on a particular day and, based on risk and within two years of commencement of the proposed legislation, the APVMA will determine the period after which the continuation application is required for the approval of active constituents.

The VFF is concerned there has been no risk framework developed that identifies which actives are considered high, medium and low risk and the re-registration timeframes around these risks.

Schedule 3 – Improving the quality and efficiency of assessment

This schedule is aimed at improving the quality and efficiency of the assessment process by allowing the APVMA to refuse inferior or deficient applications. This is supported by the VFF as a way of ensuring APVMA resources are allocated to those applications that have been developed to the appropriate standard. However, this support is conditional upon APVMA providing adequate and appropriate guidance regarding application requirements, and should not be utilised by the regulator as a barrier to the regulatory compliance process.

The use of electronic application forms is also supported. This will remove some of the administrative burden on applicants.

Shut the Gate

The VFF supports the "shut the gate" provisions that will see the APVMA no longer accepting additional data after the application has been accepted and prevent applicants from amending an application after it has been accepted. However the VFF is concerned these reforms will see permit applications rejected in the event of any deficiency, irrespective of the nature of that deficiency whether technical or administrative. We are concerned permit applicants not be exposed to the same provisions as registrants, simply due to their lack of understanding of the regulatory and application process. The VFF believes the APVMA still needs to guide and assistance permit applicants seeking emergency, research or minor use permits.

VFF believe there is a risk that an over-burdened regulator without sufficient resources will be more inclined to reject applications than facilitate them as it struggles with its workload.

This concern is heightened when in subparagraph 11A (5)(a)(iii) the APVMA is no longer required to provide a reason for why an application cannot be rectified. The VFF believes this reform will erode the transparent nature of the proposed amendments. Permit applicants should not only be notified of defects in the application but should be provided with a reason why it cannot be rectified prior to it being rejected.

Minor Use Permits

The proposed approach treats applicants for off-label minor use permits in the same manner as registrants/manufacturers. This does not appear align regulatory effort with the assessment required, particularly as the degree of risk relating to minor crops is substantially less.

As indicated previously, VFF is concerned that applications will have to be rejected in the event of any deficiency, irrespective of the nature of that deficiency i.e., whether technical or administrative. Such a regime will create additional hurdles for farmers and groups representing minor crop growers and may prevent them from gaining access to agvet chemicals in a timely or efficient manner.

The VFF is concerned at the application process as outlined, i.e., that assistance will now only be available at a cost to farmers seeking to gain a permit. Added to this will be the permit fee and any subsequent re-application fees incurred. This will add significantly to the input costs affecting already minimal returns. Particularly as farmers do not have the ability to recoup the associated costs, i.e., registrants gain the benefit of the new uses.

Overseas data

We are supportive of the use of overseas data where relevant to Australian conditions to avoid unnecessary duplication of work that has already been done to an acceptable standard. However, the VFF strongly believe the aim of any APVMA re-registration should be to assess new information about a product in a scientific manner, based on Australian conditions, and fully investigate whether industry can utilise risk management practices to address concerns, prior to APVMA forming its decision. The use of chemicals varies across Australia's many farming zones, let alone conditions and practices in counties across European or in the US. Not to mention, veterinary medicines in particular where strains of virus and parasites and environmental conditions affecting efficacy are often so different in Australia to overseas conditions. To impose a "one size fits all" regulatory measure is not appropriate. Product assessment should include comprehensive assessment of Australian risk management practices. Without these both the efficiency and confidence in the APVMA's science based risk management process will be eroded.

Schedule 4 – Enforcement

At a meeting with DAFF and APVMA representatives late last year the VFF raised the concern that a permit holder will be responsible for a permit user's non-compliance. The VFF was assured that this was an error in the draft legislation and would be amended to say that it will be the permit user who is liable for non-compliance penalties not the permit holder. When the VFF attended a roundtable in February this part of the legislation had not been changed. We are concerned that this indicates that the process is being rushed and industry concerns are not being addressed.

The VFF supports the proposed introduction of compliance tools that will allow APVMA to scale its response to non-compliance. This will include civil penalties and enforcement undertakings. A proportional response should be used over a blanket response.

The VFF supports the suspension and cancellation of approvals, registrations and permits where there is imminent risk to public health and safety however there needs to be rigorous processes in place that ensure all stakeholders, including the agriculture industry, are promptly notified of the cancellation. The VFF is concerned about what could happen to deregistered chemicals that arise as a result of the new regulations. This could see many farms with stocks of illegal/unregistered chemicals that they would then need to dispose of. There should be some consideration as to how this would occur (both the information flow and the actual disposal) and who would pay for the process.

Item 43, 173-181 addresses the powers for entry, search and seizure. The VFF considers such powers excessive and should be only exercised in the most extreme of circumstances and after due process if at all. The VFF does not support seizure of computers as the impact to the business can often outweigh the reason for the seizure. It is recognised that without computers farm businesses will cease to operate and with minimal margins any length of time could have significant impact.

Schedule 5 – Data protection

The VFF supports increased data protection measures including the 'protection period' being extended from eight years from the time of decision. This provides incentives for companies to generate data for registration and additional on-label uses. This is particularly relevant to the horticulture and grains industry.

However the VFF is concerned the data protection provisions could be exploited by some agri-chemical companies to restrict rivals from the use of key active substances to manufacture generics, under a mandatory re-registration process. This has potential to remove generic label chemicals from the market and certainly increase the cost of chemicals to the market and to Australian producers.

This concern adds further weight to our argument against mandatory re-registration.

Schedule 6 & 7– Arrangements for collecting levy/Miscellaneous

While the VFF supports any efficiencies in the levy collection, the VFF believes these funds, collected predominately from industry though levies on products, must be maintained for use by the APVMA and not become part of a collective 'pool' of levies distributed to other agencies. Efficiencies can also only be met if the 'collection fee' is not greater than the actual cost of current collection costs.

Regulation Review

If the proposed changes proceed, it is extremely important that there is an early review period, with subsequent reviews to measure the impact of the regulatory reform. As we have previously pointed out, we are extremely concerned that the reform will reduce the availability of chemicals due to market forces associated with regulatory burden. The VFF believes an early review period is warranted to ensure the amendments have provided the efficiencies sought and that there hasn't been a reduction in chemical availability as an unintended consequence.

Conclusion

While the VFF is supportive of regulatory reform that will reduce red tape and facilitate industry efficiency, we are not confident the changes proposed though this Bill will deliver those outcomes. We are supportive of the aspects of the bill that will create a more efficient pathway to chemical regulations, such as the use of overseas data, electronic submissions and 'shut the gate' provisions, but we are concerned the mandatory re-registration periods will not deliver community benefits but will increase compliance costs.

As a result of these concerns the VFF suggest the following amendments to the regulation:

1. **Abandon mandatory re-registration and retain the current triggers for chemical reviews – health and environmental concerns;**
2. **Implement the 'Shut the gate' provisions of future chemical review to ensure swift completion of chemical re-registrations. However permit applications should still be given assistance.**
3. **Review the impact of the bill once enacted.**