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Dissenting Report

Advisory Report on the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

5.1 The dissenting members have declined to support the majority recommendation of the committee:

> That the House of Representatives pass the Agricultural and Veterinary Chemicals Legislation Bill 2012 without amendment.

5.2 The dissenting members believe reform of the APVMA is overdue and are supportive of a number of the clauses dealing with the procedure and timeliness of APVMA responses to pesticide applications.

5.3 However we believe one of the bills key modifications; the intention to install a system of mandatory re-registration lacks sufficient justification and is likely to create a new layer of compliance and bureaucracy on the pesticide and veterinary medicines industry without demonstrable improvements in efficiency or outcomes and that extra costs will be passed along to Australian farmers.

5.4 The bill states one of its objectives (Key Provisions) is to reduce time-frames for processing applications and admits to backlog in processing:

> this assists in reducing the current backlog and provides for consistent and more predictable completion of assessments within appropriate timeframes".

5.5 It is of great concern to the dissenting members that the proposed mandatory re-registration process will lead to a far heavier work-load for

the APVMA and this in turn will lead to longer delays in processing, an escalation in staffing requirements and a more expensive system for little perceived gain.

5.6 The dissenting members are also greatly concerned that the department has not undertaken a cost/benefit analysis and so consequentially has little understanding of the compliance costs that will be borne by industry outside the direct administrative load. In this case the Parliament is being asked to endorse a new registration regime without understanding the full cost implications for the industries involved.

5.7 The Coalition has announced it is committed to reducing red tape and cost for business in Australia and the support of a mandatory re-registration process is not consistent with that principal.

Key issues

- While all involved in the process agreed that reform was needed to improve efficiency and speed up the review of high risk chemicals, the recommendation to pass the bill fails to adequately consider and address the valid concerns raised by grower groups and industry.
- The Bill fails to meet the efficiency test. The Department of Agriculture, Forestry and Fisheries have not undertaken a cost benefit analysis on the implications of the bill.
- The case for mandatory re-registration was not made as no specific evidence was presented of systemic failure in the current process for the ongoing registration of chemicals.
- There are significant extra costs of mandatory re-registration. The argument that additional activities could be undertaken within current staffing levels was unconvincing with the obvious burden of re-registration.
- The re-registration process doesn't target the risk and actually detracts from the regulators ability to do its job.
- Concerns were raised about re-registration of products with small niche markets that the profits derived from sales would not be sufficient to justify registration and Australian farmers would lose possibly irreplaceable tools.
- Proposed time frames are unlikely to be achievable.

Improvement in efficiency needed

5.8 Reforms were supposed to improve the efficiency of the review of suspect chemistries, reduce cumbersome assessment and registration processes and be more cost-efficient to provide industry with timely access to the best and safest crop and animal protectants.

5.9 These views were widely expressed in submissions and at the hearing.

> "We would agree with the WWF that a greater responsiveness from the regulator in this space would be a very good thing and something that is supported by our members".[1]

5.10 *And* the ANAO's inquiry into the APVMA demonstrates that the APVMA is not as efficient in the way that it conducts its work as it could be.

> The APVMA is also not meeting its obligation to finalise all applications within statutory timeframes. This increases the cost of regulation, for both the APVMA and applicants, and impacts on users' access to pesticides and veterinary medicines.[2]

5.11 This is supported by the WWF

> What we are saying is, 'Trigger a very fast process where those differences between Australia and Europe, or Australia and America—or wherever it may be—make it be considered and a resolution found very quickly.[3]

The Bill fails to prove improvements in efficiency

5.12 Consistent concerns were raised with the legislation's ability to improve efficiency:

> In fact this bill actually increases regulatory burden on the industry and imposes more work on the APVMA without any demonstrable cost/risk benefit to warrant such a move.[4]

1 Public Hearing, Cossey Croplife, p.24.
2 page 19: http://www.apvma.gov.au/about/reporting/docs/anao_audit_report_2006.pdf
3 Public Hearing, Heath WWF, p.17.
4 Public Hearing, Holdsworth, Animal Health Alliance.

> ..introduces additional processes and procedures without any corresponding improvements in regulatory efficiency or environmental or human health protection.[5]

> We are concerned that the overall benefit to the industry will be outweighed by the increase in red tape and regulatory costs associated with the re-registration process.[6]

The case for mandatory re-registration

5.13 The ANAO's inquiry into the APVMA has confirmed that we have an excellent technical and scientific regulatory system for effective management of risk:

> The ANAO concluded that the APVMA has reasonable arrangements in place to identify chemicals that require review and to prioritise the reviews according to the risk they represent.
>
> APVMA do look at what is happening around the world and if there are concerns raised about a particular chemical they do actually act and with the current review process they do that. There is a system to make sure that, if a concern is raised somewhere else in another jurisdiction or within this jurisdiction, we do look at it.[7]

Extra costs from re-registration

5.14 The dissenting members support the majority of submissions that advocate the Government's bill will raise costs and not provide sufficient gains in efficiency.

5.15 The Department does not deny there will be extra costs and this is despite Finance and Deregulation Minister Penny Wong using Agricultural and Veterinary Chemical Reform as the second key area where the government would reduce regulatory compliance costs for businesses and improve competitiveness.[8]

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5 Submission 012, CropLife, Australia, p.2.

6 Submission 003, Victorian Farmers Federation p4.

7 Public Hearing , Koval, DAFF p2.

8 Page 5 http://www.finance.gov.au/deregulation/docs/australian-government-deregulation-agenda.pdf

5.16 It is clear that the Department has under emphasised the extra costs

> The cost is that the maximum is $100 a year; $700 is what we are talking about in the draft legislation for the parliament's consideration. So, if it is a 15-year re-registration period, it is not a huge cost. But that is a commercial decision.[9]

5.17 While as the industry explains there is much more to the costs than just the registration costs.

> The APVMA's own documentation in their cost-recovery paper indicates that we are looking at an increase in the cost of the system for the proposed legislation. In fact, the 30 per cent number is the interim. They have indicated that they will probably have to do another one. Equally, the costs that DAFF were referring to are the straight-up application fees. We know that a large amount of the resourcing for this will be supported by the levies, so to suggest that the costs will be restricted just to re-registration fees does not indicate the true costs, even just to the regulator. Aside from that, administrative processes, while simple, come at a cost. If you have the regulator about to have hundreds upon hundreds of re-registrations, just to manage, file and respond to those re-registrations costs money and it takes resources away from the core input.[10]

> The bill, in its current form however, will deliver a net loss in efficiency and cannot be said in any way to address the system's failure to function within statutory timeframes. CropLife shares the concerns expressed by the farming sector, state governments and a range of other community and industry organisations that this bill, if implemented in its current form, will have a disastrous effect on agricultural productivity in Australia.[11]

5.18 The Members on this dissenting report are especially disappointed the Department Officials in the hearing admitted that the Regulatory Impact Statement failed to quantify the financial costs and financial impacts on industry. Instead it based its decision that the:

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9 Public Hearing, Koval DAFF, p.7.

10 Public Hearing, Cossey Croplife, p.26.

11 Public Hearing; Cossey; Croplife, p.23.

> …benefits outweighed the costs of the system. But it was done in a qualitative sense and not a financial sense.[12]

5.19 The APVMA's own analysis on the system demonstrates extra costs without being able to quantify any improvements due to the re-registration process.

> The APVMA's own documentation in their cost-recovery paper indicates that we are looking at an increase in the cost of the system for the proposed legislation. In fact, the 30 per cent number is the interim.[13]

Efficiency

5.20 Furthermore while delivering a net loss in efficiency it will increase regulation without targeting the risk areas:

> Yes, we would agree with that. As was indicated earlier, there are a number of products on the market that carry a higher risk profile and, in fact, the focus should be there. That is directly counter to the proposition of a re-registration system. The Productivity Commission in its review many years back indicated that that is the type of system you want: not an arbitrary across-the-board re-registration system but one that targets resources specifically to where the highest risk is. We wholeheartedly agree with that, and that in itself will add efficiency.
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> To add an entire extra level of what is, in the first case, a pure administrative process will obviously take resources away from the regulator and does not look to target those higher-end ones. Again, what we go back to is that the regulator has the powers it needs to address those risk issues. It is really about not adding more regulation—300 pages, as we have counted—but perhaps using other methods to get the regulator able to better respond in that space.[14]

12 Public Hearing, Parnell DAFF, p.9.
13 Public Hearing, Cossey CropLife, p.27.
14 Public Hearing, Cossey Croplife, p.24-25.

Re-registration

5.21 Specifically the Coalition objects in the strongest terms to the re-registration process which acts contrary to the primary aim of the bill to improve the efficiency of the chemical regulator and speed up identification and review of suspect chemicals. This is supported by the Productivity Commission report into chemicals and plastics regulation.[15]

5.22 Recommendation 8.1 states:

> The Australian Government, in consultation with the states and territories, should impose a statutory obligation on the Australian Pesticides and Veterinary Medicines Authority to ensure that:
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> - the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned,
> - its assessment priorities are directed to the most efficient management of the aggregate risk of all agvet chemicals.

5.23 The costs of the re-registration process will most likely, result in the loss from the Australian market of useful products that are safe and effective and have been used so for decades.

> Contrary to the government's claims that the re-registration process will increase the scrutiny on suspect chemistries, the increase in the administrative workload of the APVMA staff will reduce regulatory body resources available to deal with critical registrations and permits.[16]

Minor registrations

5.24 Considerable concern was raised with the size of the Australian market and the consequent incentives for potential licensees to register new or re-register safe, old, off-patent chemicals for use.

> …….. the reduction of products on the market is not because of their safety concerns or human health and environment concerns but is very much a commercial decision made on behalf of the chemical companies to not go through the re-registration process.

15 http://pc.gov.au/projects/study/chemicals-plastics/docs/finalreport

16 Submission 11, AgForce Queensland, p.5.

> So many products are moved off the market for purely commercial reasons by those organisations.[17]

5.25 Internationally our registration process is already struggling to compete and that is one of the key reasons the government sought reforms to make it more efficient. Increasing the costs will further reduce our competitiveness and force international companies to evaluate whether the costs and returns will justify the expense.

> To put the effect of this increased cost into perspective, it currently costs the same real dollar amount to register a crop protection product in Australia as it does in the United States, but the Australian market is one-tenth the size of the American market. Increased cost of registration, combined with provisions that unnecessarily increase the complexity of the regulatory system, will result in the loss of existing agchem products and discourage the introduction of newer, modern chemistry and biological products. In particular, greater regulatory costs will deprive farmers of crucial products that only have small markets, such as for minor uses and specialty crops. I know that that was mentioned just earlier and we will surely come back to that later.[18]

5.26 Small markets size already limits chemical registration in Australia because it is not economically justifiable for chemical companies and a system which increases costs through the re-registration process will further exacerbate this issue.

> The vegetable market would be the best example right around Australia. There are chemicals that are available for broccoli and other crops that are not registered here in Australia because the broccoli market in Australia is not all that big so they do not get registered. You get fewer broccoli producers so we have more imports of broccoli into Australia.[19]

> From a global perspective, for our grains industry and our ability to invest in the market failure gaps, issues around market failure particularly in this very small Australian market—we probably represent less than one per cent of the global pesticide sales—become a real challenge for us.

17 Public Hearing, McKeon NFF, p14.

18 Public Hearing, Cossey Croplife, p.23.

19 Public Hearing, Kidd NSW Farmers, p.13

5.27 and

> In Europe they have taken the decision to look at a hazard based assessment method to assess the inherent hazard of the product against particular criteria. Essentially, during the last 10 years, they have gone from 945 pesticide actives in the late 90s to about 336 in 2009, so there has been a large reduction in those against those hazard criteria. Unfortunately, a large percentage of those were eliminated because the data packages that were required to support the continued use of those products were essentially too expensive for the companies. They could not recoup on investment and so unfortunately packages were not submitted and a lot of the registrations just lapsed.
>
> Australia is a much smaller market than Europe, as you can imagine, for pesticides. The risks of course are that if we go down that particular pathway, while it is absolutely proper and appropriate to use risk based assessment, we need to look at the risks of the products and whether they are acceptable for human health and the environment, and work through that process. Unfortunately, because of the lack of investment and market failure, we have seen the acceleration of the loss of those products.[20]

Timeliness

5.28 Finally outside the re-registration process there is still scope to work with Industry and make further improvements in efficiency that will deliver tangible outcomes in efficiency and help the regulator meet its statutory timeframes. Some of the changes in Schedule 1 have been implemented purely to help the regulator meet statutory timeframes but will as a result likely retard the Industries ability to deliver new safer chemistries onto the market.

> "The rigid processes and constraints proposed in Schedule 1 of the Bill will largely remove any opportunity for an applicant to engage with the APVMA over the duration of an assessment and to provide clarifying information/data to address evaluator's questions as they arise. Similarly, the short extension periods

20 Public Hearing, Rainbow GRDC, p.31

proposed under the "maximum extended assessment periods" in the draft regulations are likely to prohibit the generation of additional data to address unforeseen information requests. These provisions are likely to condemn applications with minor data deficiencies to rejection, or alternately require applicants to pay considerable additional fees in cases where the APVMA elects to vary the application under Section 28(4)".[21]

Conclusion

5.29 In Conclusion this Bill as is drafted provides a substantial increase in regulatory burden and costs that will have a negative impact on industry without significantly improving the efficiency of regulation and the re-registration process will slow down rather than increase the review of suspect chemistries. To achieve genuine efficiencies within the system that allow for a more timely review of suspect chemistries it is vital that the proposed re-registration process be removed from the bill.

Recommendation 1

Remove the re-registration process from the bill

Recommendation 2

Set up a troika taskforce of Industry, the Department and the APVMA to urgently evaluate and improve the internal systems within the APVMA to increase the regulators efficiency and effectiveness and the speed of review of at risk chemistries.

21 Submission 014, Syngenta, p

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