competitive advantage

Inquiry: Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

Submission to:
Senate Standing Committees on Rural and Regional Affairs and Transport

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SUMMARY

The *Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012* contains many improvements. However, there are aspects of the Bill that are of concern:

1) The objective of providing a 'cost effective, efficient, predictable, adaptive and responsive' regulatory system will not be achieved without clear guidance as to what is constitutes acceptable risk. The Bill needs to:
   a) Acknowledge and accept that there are risks associated with the use of agricultural and veterinary chemicals.
   b) Define what risks are acceptable and what constitutes unacceptable risk.
   c) Require, where a product is already available for use in Australia for non-APVMA regulated uses, that APVMA take into consideration the current use of the product and clearly articulate to the applicant, prior to submission of the application, what additional data will be required and justify why the additional data are required.
   d) Require, where a product is already registered by regulators in countries with comparable standards for health and safety to those in Australia, that APVMA clearly articulate to the applicant, prior to submission of the application, what data not required in the other countries in which the product has been registered and is being used will be required and justify why the additional data are required. The requirement for justification is important as innovators of novel products may be able to satisfy APVMA requirements in other, perhaps better, ways if they understand why the information is required.

2) Re-registration/re-approval will help ensure information in APVMA's files are current and will give registrants/approval holders an opportunity to confirm the information in APVMA's files is current. However, a re-registration/re-

approval program will result in loss of products as approval holders and registrants decide to not supply new data if APVMA requests new data not required by other regulators. It is recommended that:

a) APVMA be required to rely on overseas reviews and to only undertake a technical review if there are specific conditions within Australia that might alter conclusions made by other countries.
b) APVMA be prevented from requiring data not required by regulators in countries with comparable standards for health and safety to those in Australia without providing details of why the data are considered essential and why they were not required by other regulators.

3) Companies are likely to have their ability to develop new products or new uses for existing products unless they successfully challenge infringement notices in court as APVMA is prevented from issuing a permit to anybody who has been required to pay a pecuniary penalty within the previous 10 years. The cost of challenging such penalties is likely to result in smaller companies, including consultants and contractors who assist other companies to develop and register their products, more than larger companies. To minimise the impact on business, especially small business, it is recommended that the Bill be amended to:
   a) Ensure registrants of products obtain permission from the approval holder for any active constituent they wish to use in their registered products before registration for the proposed products is granted. This will reduce the risk of an overseas supplier providing product that would result in enforcement action being taken by APVMA.
   b) Prevent use of active constituents from approved sources without authorisation of the approval holder and nominated person. As above, this will reduce the risk of an overseas supplier providing product that would result in enforcement action being taken by APVMA.
   c) Remove liability of the nominated person for offences by an overseas supplier that the nominated person has no control over, e.g. if an overseas supplier supplies a registered product with an unapproved label to a third party without the knowledge of the nominated person.

BACKGROUND

The *Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012* has been referred to the Senate Standing Committees on Rural and Regional Affairs and Transport. This submission addresses some issues and concerns about the *Bill*.

ISSUES

Initial assessment and registration processes (Schedule No. 1 of the Bill) including factors that affect efficient regulation, including the risk assessment process.

The Bill 'recognises that … the present and future economic viability and competitiveness of primary industry … relies on access to chemical products and their constituents' and that there is a need for a 'system for regulating chemical products and their constituents that is cost effective, efficient, predictable, adaptive and responsive'.

These are laudable objectives that will not be achieved without clear guidance as to what constitutes acceptable risk.

Many new, reduced risk agricultural and veterinary chemical products are being developed by smaller companies. Not infrequently these companies rely on venture, equity or other investor funding. Eventually some of the more successful organisations can be acquired by larger companies. Bayer's acquisition of Agraquest is an example of a successful, small company being acquired by a major company.

Products being developed by smaller companies have low probability of being registered in Australia as the system for regulating products:

- Is not cost effective (given the size of the Australian market); and
- Is not predictable.

As a result of the regulatory system not being cost effective and being unpredictable, investors are unwilling to support projects that will require registration of products in Australia. As an example, Joe Hudson of One Earth Capital (a US based venture capital fund) told me venture capital funds will not invest in projects in Australia unless there is certainty about the cost of obtaining regulatory approvals and certainty about the time required to obtain those regulatory approvals.

Lack of certainty and predictability resulting from demands for additional data.

The lack of certainty about cost and time results from unpredictable requirements. Currently the regulator (APVMA) not uncommonly requires data for new/novel products that have not been required by regulators in other countries. Such requests, normally made after applications have been submitted to APVMA:

- Result in additional costs to applicants; and

- Significantly delay final registration of products.

APVMA has proposed a system of consultation prior to submission of an application. The opportunity for such consultations is welcomed but the proposal to limit consultation to one such meeting is too restrictive.

With novel products, there may be a need for the regulator to become acquainted with such products before being able to provide meaningful guidance. A single meeting may be insufficient to enable the regulator and the applicant to become adequately familiar with the products and to understand how best to satisfy the needs of the regulator.

Similarly, submitting requests for advice as a Category 25 application, which is APVMA's current preferred option for obtaining advice, is impractical as timeframes for APVMA giving guidance are the same as those for registration. As a result, a Category 25 application can take as long as registration, i.e. requesting information under Category 25 can more than double the time required to obtain registration of a new product.

Lack of certainty and predictability resulting from differences in requirements between regulators within Australia

There are inconsistencies in data requirements between different regulators within Australia. The following are examples:

1. A cleaner can be available for use in the home (regulated by TGA if also a disinfectant) and/or to clean milk tankers used to transport milk from the farm (regulated by FSANZ if residues likely to enter the milk or by TGA if also a disinfectant with no possibility of residues in food) as well as in the milk factory that processes the milk (regulated by FSANZ if residues likely to enter the milk or by TGA if also a disinfectant with no possibility of residues in food). However, if that same product is to be used as a dairy cleanser in on-farm milking equipment, milk storages, etc. (which are regulated by APVMA), registration by APVMA will require significantly more data than is required for authorisation of those products for use in other situations. The cost of generating such data can be significant and is preventing companies registering products for on-farm use.

2. Certain micro-organisms have beneficial effects in promoting growth of plants. Those same micro-organisms can inhibit or control pests and/or plant diseases. These micro-organisms can be imported into Australia and used after obtaining an AQIS permit. If those products are to have an APVMA regulated claim such as suppression or control of harmful pests or diseases added to the label, significantly more data are likely to be required even though the products will be used in the exact same way and at the same rate of application and timing of application as for non-APVMA regulated uses. The additional costs of APVMA registration are discouraging companies from commercialise their products in Australia or forcing them to seek ways of commercialising products without the need for APVMA registration, including restricting claims to uses such as 'soil amendment'.

It is often difficult for applicants to understand or justify why APVMA requires additional data especially when the same products are registered overseas and are used overseas without adverse effect and may even be used in Australia for non-APVMA regulated uses without adverse effects.

The uncertainty about data requirements frequently results in registration of products not being pursued in Australia, i.e. the uncertainty results in these products not being made available for use in Australia.

The uncertainty results from APVMA requesting data that:

- Has not been required by regulators in other countries.
- Has not been specified in APVMA guidelines.

The uncertainty about data requirements includes:

- What data will be required;
- The cost of generating the required data; and
- The time required to generate the data.

Recommendation:

To give clarity to the Regulator and to the regulated community, the Bill needs to:

1. Acknowledge and accept that there are risks associated with the use of agricultural and veterinary chemicals.

2. Define what risks are acceptable and what constitutes unacceptable risk.

3. Require, where a product is already available for use in Australia for non-APVMA regulated uses, that APVMA take into consideration the current use of the product and clearly articulate to the applicant, prior to submission of the application, what additional data will be required and justify why the additional data are required.

4. Require, where a product is already registered by regulators in countries with comparable standards for health and safety to those in Australia, that APVMA clearly articulate to the applicant, prior to submission of the application, what data not required in the other countries in which the product has been registered and is being used will be required and justify why the additional data are required. The requirement for justification is important as innovators of novel products may be able to satisfy APVMA requirements in other, perhaps better, ways if they understand why the information is required.

Re-approval and re-registration of agricultural and veterinary chemicals (Schedule No. 2 of the Bill) including the need for re-approval/re-registration and the process and practical effects.

Re-registration and re-approval is necessary to ensure the Regulator has current information and registrants/approval holders know the regulator has up to date information. However, Australia is a small market for agricultural and veterinary chemicals and imposition of excessive costs for re-registration/re-approval will result in many currently available products being taken off the market.

Costs for re-registration/re-approval include:

- Fees payable to the regulator.
- Cost of any additional studies that need to be conducted.
- Cost of time in collecting and collating required information.

Imposing requirements for new data to support re-registration/re-approval that are not required in other, larger markets will result in registrations and approvals being cancelled as companies decide the cost of providing data exceeds potential returns. Australian primary industry will see products lost and, Australian farmers will be placed at a disadvantage to their overseas competitors if the regulatory system continues to discourage registration of novel products that are already available to farmers overseas.

Comprehensive re-registration programs operate in other countries. The Bill recognises that other countries are reviewing products when it states at Section 46A that the duration of approval of an active constituent can be varied 'if 2 or more foreign regulators have prohibited the use of the active constituent on safety grounds'.

Recommendation:

1. APVMA should be required to rely on overseas reviews and to only undertake a technical review if there are specific conditions within Australia that might alter conclusions made by other countries.

2. APVMA should be prevented from requiring data not required by regulators in countries with comparable standards for health and safety to those in Australia without providing details of why the data are considered essential and why they were not required by other regulators.

International comparisons and trade issues, including the effect on small companies.

The Bill states that a person acting on behalf of non-residents is held to have the same liability as the non-resident and is punishable accordingly. This is not significantly different to the current legislation. However, the implications under the proposed new legislation are significant.

The Bill introduces new enforcement tools, including infringement notices. The issue of an infringement notice can result in a company being prevented from developing new products for at least 10 years:

- Section 145DE states that payment of an infringement notice is not considered an admission of liability.
- Section 112(4)(b)(vii) states 'APVMA must also refuse the application [for a permit] if it is satisfied that … [the nominated person] … has, within the 10 years immediately before the application … been ordered to pay a pecuniary penalty for the contravention of an agvet penalty provision'.

- Permits are required to use an unregistered product or a registered product for an unapproved used, including testing new products and developing existing products for new uses.

The result of paying a fine associated with an infringement notice is exclusion from holding any permit for at least 10 years, whether the person admits liability or not.

Furthermore, the infringement notice may be issued for a matter that the nominated person has no control over, e.g. an overseas company may supply product (e.g. with an unapproved label or in packaging labelled with an approved label but containing an unregistered product) to somebody without the knowledge of the nominated person. As the nominated person is liable for payment, that person could be prevented from holding a permit for 10 years.

Smaller companies have limited resources to challenge APVMA in court. This will result in smaller companies being affected by infringement notices more than larger businesses that can afford to defend themselves in court.

Similarly, consultants and other businesses that assist in the development and registration of agricultural and veterinary products may have their ability to operate severely impacted by an overseas client, for whom they are the nominated person, doing something that results in APVMA issuing an infringement notice.

The Bill has considerable potential to result in the businesses of local companies being severely restricted by:

1. Making them liable for payment of pecuniary penalties whether an offence occurs with or without their knowledge.
2. Preventing them from holding a permit for 10 years as a result of them having paid a pecuniary penalty, whether they admit liability or not.
3. Preventing them from conducting business development activities that require a permit due to them being prevented from holding a permit.

Recommendation:

The Bill should be amended to:

2) Ensure registrants of products obtain permission from the approval holder for any active constituent they wish to use in their registered products before registration for the proposed products is granted. This will reduce the risk of an overseas supplier providing product that would result in enforcement action being taken by APVMA.

3) Prevent use of active constituents from approved sources without authorisation of the approval holder and nominated person. As above, this will reduce the risk of an overseas supplier providing product that would result in enforcement action being taken by APVMA.

4) Remove liability of the nominated person for offences by an overseas supplier that the nominated person has no control over, e.g. if an overseas supplier supplies a registered product with an unapproved label to a third party without the knowledge of the nominated person.