Agvet chemicals regulation reform

2015 issues and ideas for discussion

Context

The Department of Agriculture has developed this paper to guide discussions with stakeholders in agricultural chemicals and veterinary medicines (agvet chemicals) regulation. Beginning this discussion process reflects a number of current imperatives in agvet chemical regulation policy including:

- stakeholder desire for government to consider reforms creating a more modern, responsive and flexible regulatory environment;
- the government's stated intention to improve the function of the regulatory system, decreasing the regulatory burden on business where possible;
- the continuing process of consideration of broader chemicals regulation reform by the Council of Australian Governments.

We ask that you consider the policy issues raised in this paper and the list of potential reform ideas as the beginning of a process that will require the knowledge and experience of the stakeholder community if significant and successful reform is to be achieved. These potential reforms reflect ideas that have been put forward by chemicals and farm industry, chemical users and community groups. The department has begun discussing these reforms with the Commonwealth regulator, the Australian Pesticides and Veterinary Medicines Authority (APVMA). But they do need to be tested by the wider group of stakeholders.

We also ask that you consider, and share with the department, the expected costs and benefits for your business or organisation resulting from reforms, including any red tape savings or burdens.

In putting forward these ideas, the department recognises the significant program of implementation of recent reforms being undertaken at the APVMA, as well as the APVMA's development of further operational reform opportunities. The department will continue to work with the APVMA to ensure the most effective reform pathways are pursued.

The department is looking for your views, both formal and informal, about future regulation reform.

The case for reform

The Commonwealth regulates agvet chemicals in collaboration with the states and territories. The APVMA approves chemicals for supply, sets conditions for their import, manufacture, supply and use and enforces compliance up to the point of retail sale. The states and territories control the use of chemicals after they are sold according to the conditions for their use set by

the APVMA while the APVMA ensures the chemicals that are sold meet appropriate standards.

This model emphasises pre-market assessment to manage chemical risk through a detailed examination of data provided by a prospective supplier and by prescribing conditions for using the chemical. The approach relies on the willingness of prospective suppliers to meet regulatory requirements that may be unique to Australia. The system depends on effective monitoring of chemical suppliers by the APVMA and control of chemical use by the states and territories.

Chemical manufacturing, agricultural production and consumer demands have changed a great deal since the establishment of the agvet chemical regulation system in the 1980s. While fit for purpose when it was designed, the regulatory system has not kept pace with this change. The system continues to provide for the safe use of agvet chemicals, but parts of the system impose unnecessary costs that do not deliver additional benefits in risk management.

Over the last 30 years there have been significant changes to the environment for agvet chemicals regulation:

- State and territory governments have far less capacity to monitor and enforce compliance.
- The manufacture and supply of chemicals was once done mostly by domestic formulators with a small range of chemical products. The market is now dominated by a few global companies, only one of which is Australian. Generic imports from China and India are prominent in a market with a greater number of products.
- Agricultural supply chains are now more vertically integrated and produce markets are more concentrated. Increased effort and expertise on quality assurance in supply chains means producers are increasingly expected to proactively manage chemical risk.
- Agricultural production is more diverse and specialised. Consumers want a greater variety of food and are concerned about the source and quality of the food they are consuming.
- The continuing challenge of pests and weeds developing resistance to existing chemicals requires the ongoing rollout of new chemical modes of action. Biosecurity and sustainability concerns drive demand for new tools to address weeds and pests.
- Increased exposure to global competition, steady terms of trade and slowing productivity growth have increased pressure on agrifood producers to reduce input costs and introduce new chemical technologies.
- The fast moving consumer chemicals sector has become even faster. This sector has different characteristics, risks and needs from the agricultural chemicals sector.

These changes mean chemical users are seeking faster access to newer, more effective and safer chemicals. Chemical companies want more predictable, transparent and lower cost regulation. The requirement to ensure chemicals can be used safely remains. Any opportunities to more efficiently deliver and/or improve safety outcomes should be explored.

Delivering long-lasting reform – where do we start?

An effective and efficient regulatory regime ensures appropriate management of risk while allowing for the safe use of products, without unnecessary costs or red tape. Regulation that imposes unnecessary costs and regulatory burden and does not match regulatory effort with risk wastes resources, reduces users' competitiveness and sustainability, discourages industry innovation, encourages an unresponsive, uncompetitive market, and can risk regulatory failure.

Reform must begin with an understanding of current arrangements, their successes, failures and opportunities to improve. This, when combined with an understanding of the current environment for reform and of how that environment has evolved (discussed above), will allow stakeholders to identify and develop the reform ideas of greatest benefit. These ideas should be tested against appropriate reform objectives. The department considers stakeholders might consider these objectives should include:

- aligning regulatory effort and burden with chemical risk, improving regulatory efficiency and reducing unnecessary red tape
- improving access to chemicals, both new uses for existing chemical products and new chemicals entering the market
- improving the national system for regulating chemicals

As noted above, over the past five years the department has received input from agvet chemical stakeholders along the supply chain about changes they would like to see to the regulatory regime that could improve the way they do business. Recognising the current opportunity to update and improve the system the department has reviewed this input to identify themes and ideas for consideration and possible development. The identified ideas that would contribute to the objectives described above are briefly described in the attachment.

Next Steps

You are encouraged to contact the department at any stage to discuss your views about this paper and ongoing reform, including your support or otherwise of the ideas we have put forward and any other issues you would like considered.

The department is very keen to hear your views, formally or informally. We would be happy to take your calls, meet with you to discuss or to receive written or emailed comments.

Your first point of contact should be Lachlan Ice, Policy Officer, Agvet Chemical Regulation Reform, Australian Government Department of Agriculture.

You can reach Lachlan on (02) 6272 4060 or lachlan.ice@agriculture.gov.au

Reform ideas for further development and prioritisation

Building on experience, expertise and analysis of input from development of previous reforms, including stakeholder engagement relating to these reforms, the department has identified the following initial ideas for reform. These do not reflect government priorities or policy positions. Our intention is that a package of measures will be put forward for government consideration only when stakeholders have had full opportunity to contribute to the development of reform proposals.

Where proposed reforms relate to the APVMA's current activities to increase operational efficiencies, the department will work with the regulator to ensure work to date is recognised and to determine the best approach to any further reform.

Reforms (a) to (i) below are focussed on aligning regulatory effort and burden with chemical risk, improving regulatory efficiency and reducing unnecessary red tape. These measures could reduce the cost of bringing chemicals to market and improve access to new uses of chemicals:

a. Explore use of overseas information, assessments and decisions to fast track assessments of products already registered overseas. Implementation could be done in various ways including:
   i. Using international assessments for a product's human, animal and environmental health risks and efficacy with full assessments of product risks unique to Australia.
   ii. Alternatively, no longer assessing products that are registered by trusted regulators overseas where the risks of using the product are the same as in the overseas market. This approach would require support from industry to change legislation and to develop an alternative approach to deal with international trade risks.
   iii. A combination of the first two options with low to medium risk products being registered solely on registration in international markets from similar regulators. Higher risk products could be assessed as outlined above in option i. or assessed fully as they are currently.

b. Reduce the scope of products regulated by the APVMA:
   i. No longer registering some products of limited regulatory concern (for example sanitisers and disinfectants), building on the benefits recently delivered in similar reforms to the regulation of animal feeds.
   ii. Taking a lighter touch for regulation of some other products (that pose different risks but do not require a full assessment, for example cat and dog products registered overseas), including allowing self-registration of some products.

c. Work with industry to explore expanding the range of products not requiring efficacy assessments by the APVMA.

d. Discuss APVMA trade assessments with industry to determine whether the scope of these assessments should be reduced or whether trade risks are better handled directly by industry.

e. Expand uses of existing products by crop and pest grouping, data extrapolation and representative crops (eg allow use on all pome fruit if approved for use on green apples).

f. Consider how the past good compliance and safety record of trusted registrants could reduce the regulatory burden on those trusted registrants. Explore ways of reducing red tape on trusted registrants.

g. No longer separately approve active ingredients. Establishing standards for active constituents in chemical products.
    i. The APVMA currently assesses some active constituent risks when they are approved and again when it registers chemical products containing that active constituent.
    ii. Current arrangements may impose unnecessary duplication and costs and limit product manufacturer's ability to competitively source product inputs.

h. Explore the potential to build on existing APVMA work to in-source health and environment assessment services. Allow for contestable provision of assessments to applicants by accredited suppliers. Consider removing duplication in regulation of agvet chemicals developed using gene technology.
    i. This approach could reduce APVMA's costs.
    ii. Would allow for greater predictability for the timing of chemicals getting to market.

i. Cease issuing APVMA export certificates and export and import permits.
    i. These processes impose unwarranted costs and time delays.
    ii. Certificates issued to facilitate trade could be issued by bodies with trade as a focus.

The reform below, along with (a), (c), (d) and (e) above are focussed on improving access to chemicals to address the minor use issue and reduce chemical cost. This measure requires greater involvement of the states and territories in reform than measures (a) to (i) above, represent a more fundamental shift in regulatory approach and is more challenging to develop and implement.

j. Consider how we get the right balance between pre-market access assessment and post-market compliance and monitoring to manage the risks of chemical use.
    i. Identify opportunities to improve access and safety outcomes while recognising and supporting industries ability and interest in good stewardship.
    ii. This reform would leverage the effectiveness of other risk controls like industry codes, quality assurance and food safety systems, consumer law, product stewardship and good industry practice.
    iii. The reform would embrace co-regulatory approaches to managing chemical risk.

Further measures focussed on improving the national system for regulating chemicals.

k. Consider including a net benefit test (including social, economic and environmental considerations) when assessing the impact of removing a chemical from use via review (eg considering whether the net environmental consequences of a decision to remove use of a herbicide are likely to be greater than the consequences of retaining the use—perhaps substitute weed management strategies could have worse environmental impacts).

l. Consider the problems that arise with compounding and how to maintain the integrity of the regulatory system to manage risks (particularly) to animal health.

m. Reviewing and correcting legislative inconsistencies identified during consultation. Addressing any outstanding legislative issues with existing reform implementation.