SUBMISSION

GPA response to the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017.

Date 19 July 2017
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Thank you for the opportunity for Grain Producers Australia to provide a response to the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017. The grains industry represented by Grain Producers Australia (GPA) represents Australia's broadacre, grain, pulse and oilseed producers at the national level. GPA was created to foster a strong, innovative, profitable, globally competitive and environmentally sustainable grains industry in Australia. The objectives of GPA are to establish a strong independent national advocate for grain producers based on a rigorous and transparent policy development process; engage all sectors of the Australian grains industry to ensure operation of the most efficient and profitable grain supply chain; and facilitate a strategic approach to Research, Development and Extension intended to deliver sound commercial outcomes from industry research.

GPA has an industry leading policy council which is supported by the following members from VFF Grains Group, NSW Farmers Association, Agforce Grains, Grain Producers SA, TFGA, WAFF, WAGG along with 3 elected growers from the North, South & Western region of Australia. GPA now represents some 5219 farm Business members across Australia.

GPA has been engaged for many years in cross industry discussion in relation to increasing market failure of commercial investment in agricultural pesticides and veterinary medicines (AgVet) in Australia. Key relevant GPA responses previously submitted include:

- **Response to Department of Agriculture Proposed Agricultural & Veterinary Chemicals Legislation Amendments Consultation Paper (7th March 2014)**
- **Response to Australian Government Senate Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014 (17th April 2017)**
- **Response to Australian Government Agricultural Competitiveness Issues Paper (17th April 2014).**
- **Grain Producers Australia response to Department of Agriculture First Principles of Cost recovery at the APVMA final report (24 October 2014).**

Australia is no longer on the global priority list for pesticide and veterinary medicine investment in commercialisation as it was 20 years ago. It is essential that unnecessary reviews and red tape does not further erode Australian AgVet investment and resulting productivity through reduced technology access. It is important that APVMA reviews are based on science-based evidence where adverse events or new international scientific evidence calls for reconsideration of existing chemical actives.

The Australian grains industry is not resourced to meet the potential significant cost of an unnecessary regulatory process where time bound compulsory re-registration is likely to result in commercial market failure for regulatory support of generic off patent chemical actives. Australia is also missing out from productivity improvement through commercial investment in a large number of potential emerging biological, biochemical and biotechnology based AgVet technologies. It is essential that Australian
grain growers have access to the same pesticide technologies to remain internationally competitive with other overseas producers.

While GPA is responding mainly positively to the key changes in the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017, the key deficiency of the proposed changes is that it does not address the declining commercial pesticide investment into Australia.

**Key Messages In Summary:** There is a clear need for a cross industry initiative to address the complex discussions between government, agricultural industries, community beneficiaries, APVMA and commercial registrants. GPA recommends the establishment of a cross industry task force to deliver Improved technology Access for Agricultural Production.

To address the key strategic issue of productivity impacts from declining technology access, as previously detailed in the three government submissions in 2014, as previously detailed, GPA recommends that the government urgently address the following:

1. Establish a cross industry task force for improved technology access for agricultural production
2. Provide government leadership in further delivery and investment in a cross industry minor use and specialty production initiative, expanding on the now established AgVet Collaborative Forum, which should be jointly managed by cross industry research and development corporations
3. Consider increased international partnership in co-regulation and look for efficiencies and incentives for AgVet investment in Australia
4. Consider future regulatory reforms to underwrite these opportunities and initiatives.

Consultant Dr Rohan Rainbow, also a consultant to GPA, has previously facilitated discussions with most of the agricultural industry RDCs, Department of Agriculture and Water Resources, APVMA and key registrant groups CropLife Australia and the Animal Medicines Australia to identify the major factors resulting in declining investment in Australia which include:

- Australia is a small market in a global context < 1.5%
- Since the last round of AgVet reforms in 2014, Australia is continuing experiencing difficulties with complex AgVet regulations, timeliness and costs relative to commercial return on investment
- Global multinational companies face a poor rate of return on commercialisation investment compared with major developing markets including Brazil and China.

The impact of this declining investment is highlighted in table 1 comparing differences in pesticide technology access for Australian grain growers with the USA. This data clearly identifies a significant problem from a lack of investment as growers are impacted by the ‘double whammy’ of lack of new, more advanced pesticide options delivering productivity outcomes, plus accelerated selection pressure for pesticide resistance due to a narrow pool of products.

This situation has not improved since 2014 and commercial investment in new pesticide technologies appears to have become worse in the last years. Recently in May 2017, GPA conducted a telephone interview survey of six multinational chemical companies focusing on direct impacts to the grains industry from the Federal Government APVMA relocation policy and resulting outcomes to the grains industry from impacts of APVMA staffing resources and delivery timeframes. The consensus of these interviews to four questions, aggregated to avoid commercial in confidence issues are detailed in the following responses:
Table 1. Comparison of first registered labels between Australian and USA.

<table>
<thead>
<tr>
<th>Compounds</th>
<th>Type</th>
<th>Trade name</th>
<th>Australia – Initial registered Uses</th>
<th>USA – Initial Registered Uses</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syngenta</td>
<td>Fung</td>
<td>Sedaxane</td>
<td>Barley, oats, triticale &amp; wheat</td>
<td>Canola, Cereal Grains, Corn, Soybean</td>
<td>2012</td>
</tr>
<tr>
<td>BASF</td>
<td>Herb</td>
<td>prosulfuron</td>
<td>Casper Turf</td>
<td>Field corn, pop corn, sorghum</td>
<td>1995</td>
</tr>
<tr>
<td>Syngenta</td>
<td>Herb</td>
<td>Saflufenacil</td>
<td>Pre-plant BL weed control</td>
<td>Cereal Grains; Citrus; Cotton; Folage of Legume Vegetables, Forage, Dodger, &amp; Straw of Cereal Grains; Grape; Legume Vegetables; Pome Fruit; Stone Fruit; Sunflower; Tree Nuts</td>
<td>2009</td>
</tr>
<tr>
<td>Bayer</td>
<td>Herb</td>
<td>Pyroxsulfone</td>
<td>Sakura</td>
<td>Corn, soybean</td>
<td>2012</td>
</tr>
<tr>
<td>Bayer</td>
<td>Herb</td>
<td>Foramsulfon</td>
<td>Tribute Turf</td>
<td>Corn, turf</td>
<td>2003</td>
</tr>
</tbody>
</table>

Source: compiled by Kevin Bodnaruk AKC Consulting Pty Ltd for Horticulture Innovation Australia Limited

1. Have there been any delays from the current APVMA approval timeframes that has resulted in a new chemical not being available to the grains industry in the 2017 season (Yes/No).

Response - Definitely yes - This will result in companies missing at least 1 season and potentially 2 (with a 12 month delay that has occurred on several products). All companies had examples of at least one or more new product applications that will miss the 2017 season for growers as a consequence of the delays. It appears that the grains industry will have a delay of at least 3 major new herbicide/fungicide actives which will result in a collective minimum direct loss through lack of the technology benefits these products deliver to grain growers of at least $200 million and up to $500 million, compounding if pesticide resistance evolution that these new products resolve tracks faster than expected. Assessments have significantly slowed since November, particularly OH&S/Health and Environment.

2. How many additional months delay on statutory approval timeframes are companies now factoring into their business decisions i.e. 3/6/9/12 months?

Response - Definitely yes - Minimum of 5 months to over 12+ months. Companies estimate this to be at least 6 months at the moment, but most companies expect this to increase to 12 months by the end of the year

3. Have the recent approval delays resulted in decisions to terminate or delay investment decisions for new products for the grains industry (Yes/No).

Response - No, not yet - However there have been a number of companies that have already delayed application decisions to better match return on investment and enable the APVMA to focus on existing priority assessments. Most companies indicated that there would be an impact on future Australian chemical development investment if the situation continues, potentially with increased prioritisation focusing on major industry new products in Australia if the situation continues. This issue will potentially have a very significant impact on minor use industry needs, unraveling much of the progress made through the AgVet Collaborative Forum and Assistance Grants Program– Access to Industry Priority Uses of AgVet Chemicals.
4. Have the recent delays resulted in a reprioritization of application investment and/or reprioritisation of individual company applications for APVMA approval to manage the lack of resources (Yes/No).

Response - Yes - This was unanimous for every company. To mitigate the risk to priority projects, all companies have sought a reprioritisation of applications for APVMA assessment to address the lack of APVMA assessment resources. It was noted by couple of companies that they were resorting to multiple applications/assessment pathway options for the same high priority product to try and mitigate risks of current assessment timeframes, however this adds cost and doubles the use of the limited APVMA assessment resource.

To summarise:

- Companies indicate they would like to be optimistic and recognise that there is still time to recover some of the impacts from the current situation
- Consensus is that it look likely that the delay situation is likely to become much worse over the next 2 years - resulting longer term impact is likely to result in reduced overall development investment
- It is likely to take up to 5 years for the APVMA to recover from the current lack of technical staff resources, with all companies noting there is a global shortage of regulatory experts
- If the situation lasts for another 2 years with a delay of 12 months on major projects, the minimum impact through lost productivity and accelerated pesticide resistance evolution to the grains industry will be well over $1 billion.

This is clearly an unacceptable situation for the grains industry. GPA recognises that the impacts to horticulture are likely to be even greater. There is a need for an urgent roundtable to consider options to resolve this situation involving the Federal government, agricultural industry, registrant companies and the APVMA.

As previously detailed in the 2014 GPA submissions listed above, the identified outcomes for community and industry that need to be achieved include:

- Increased National and foreign investment in Australia
- Increased agricultural profitability and sustainability
- Increased delivery of a diverse range of foods to a multicultural community
- Increase productivity and scale of industries contributing to GDP and balance of trade
- Improving safety to community, environment and trade.

Potential options for addressing increased investment in Australia have been identified which include:

- Improved prioritisation
- New incentives for investment
- Co-investment partnerships
- Increased clarity on benefits and return on investment
- Regulation co-equivalence opportunity
- Clarity of roles for commercial companies, RDCs and regulators
- Regulation reforms.
The proposed regulatory reforms detailed in the exposure draft for the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 appear only to address a number of issues created through the last round of legislative reforms. There is clearly a need for further legislative reform to deliver technology access outcomes for Australian agriculture including grain growers. GPA provides the following comments on the exposure draft.

**Comment on clarifying confidential commercial information provisions.**

The proposed exposure draft details changes to address CCI issues at the APVMA for regulatory decision purposes, however the resulting impacts of these changes are unclear. GPA understands that the exposure draft amendments will enable APVMA staff to undertake the necessary assessment tasks without punitive risk outlined. The proposed exposure draft does not appear to have addressed CCI issues for industry previously raised by GPA. GPA has concern that the proposed changes/or lack of clarity of impacts could potentially make the current situation worse, particularly for commercial registrant support for minor and emergency use permits.

The proposed changes have not addressed issues previously raised by GPA in regards to data protection, which is likely to be compounded by the proposed CCI provision changes. The current AgVet code does not provide data protection on permit applications, while many applications also require reference to data under CCI. This is of particular concern to the grains industry in addressing many permit applications in development through the AgVet Collaborative Forum, which will require some CCI data on generic products and in particular those that are near end of patent protection. In addressing CCI, consideration must also be given to the data protection provisions for permit applications. Without this, there are likely to be significant issues with ongoing commercial support for delivering industry outcomes on minor and emergency permit applications, including prioritised projects identified through the AgVet Collaborative Forum, and work underway financially supported through the Federal Government AgVet grants program.

The issue of CCI and data protection does not appear to be satisfactorily resolved with the proposed changes as there is a lack of clarity of the potential commercial investment impacts. GPA recommends that further stakeholder consultation with registrant and producer industry stakeholders take place in regards to the proposed CCI exposure draft on potential options and solutions.

**Comment on adding the potential for human exposure to antimicrobial resistant microorganisms as a specific safety consideration.**

GPA has concern in regard to the proposed potential regulation to manage antimicrobial resistant microorganisms. While there are currently no antimicrobials registered in Australia for use in plant industries, there may be a strategic need in the future, particularly in response to an exotic pest incursion due to a biosecurity breach. Antimicrobials are registered for use in plant industries in other countries including the USA and New Zealand. GPA has previously made submissions to the AgVet Chemical Task Group on the issue of providing simple pesticide resistance warnings which reinforce industry stewardship and resistance management programs. This includes the risk of accelerated resistance evolution from the use of reduced application rates. Antimicrobials are similarly at risk from reduced application rate practices. However to specifically legislate on pesticide resistance management, either in plant, animal or human health is completely inappropriate as the biological evolution of pesticide resistance is well beyond the control of the user, and resistance is more broadly impacted by local and international industry whole of industry use. Pesticide resistance is therefore broadly beyond the immediate control of the industry and individual user and so only general advisory notices or warnings can be given. GPA proposed these types of notices to the AgVet Chemicals Task Group in stakeholder discussions and a formal submission, however this proposal was rejected. It appears that a proposal

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1 GPA response to AgVet Chemicals Task Group discussion papers: access to agricultural chemicals and minimum training and licensing requirements - 28 November 2016.
for a legislative approach specifically for managing antimicrobial resistance risk to human safety is being proposed which would be at odds with the proposed COAG control of use approach.

GPA would not support a legislative approach to managing pesticide resistance, which includes the use of antimicrobials. GPA would support the use of pesticide resistance warnings through an industry agreed stewardship and resistance management program.

Other exposure draft proposed changes

GPA supports the proposed approach as detailed in the exposure draft and consultation document;

- Simplifying reporting requirements for annual returns.
- Increasing the APVMA’s flexibility to manage minor errors in applications at preliminary assessment.
- APVMA amendment of the relevant particulars or conditions in a variation application.
- Timeframe for notifying FSANZ about variations to the MRL Standard.
- Enabling a person to vary the particulars of a label approval that is suspended.
- Amendments to the definition of ‘expiry date’.
- Including civil penalty provisions for false or misleading information.
- Other minor and technical amendments to the Agvet Code and the Administration Act.

Other comments for future AgVet legislative reform

As previously detailed in previous submissions to the Department by GPA, Agriculture is facing significant challenges in being able to deal with the future resistance threats and emerging plant and animal health issues. Many agricultural industries, particularly grains will experience significant productivity losses in 8-10 years through the combined impacts of pesticide resistance evolution and the limited access to new technologies. With a lead-time of 7 to 10 years to deliver a commercial technology that has already demonstrated proof of concept, Australia cannot afford an increased burden of unnecessary costs.

Options that could be implemented through further legislative AgVet reform delivering productivity outcomes for industry including an improved approach to minor use and specialty needs of pesticide and veterinary medicines have been proposed following consultation with many RDC’s and peak industry bodies. These options include;

1. Further Federal Government support and legislative incentive to build on the now established cross agricultural industry minor use program known as the AgVet Collaborative Forum broadly supported by all Australian plant industry RDCs resulting in;
   - Improved priority setting and cost sharing
   - Achieving Government, RDC and Commercial co-investment in data generation
   - Achieving cost savings through cross industry efficiencies and international collaboration and co-investment with IR-4 USA and Canada

2. Following establishment of formal collaboration with USA and Canada through IR-4 minor use programs, establish an Australian minor use program cost recovery model which mirrors these overseas programs;
   - Delivering cost savings, which would need to be based on co-equivalence of cost recovery models for evaluation
   - Delivering technology to agricultural industries faster
• Increasing international confidence of Australia as a cost effective investment option

3. Establish provisional and/or conditional registration system with fee payment deferral options based on agroecological co-equivalence and same use in crops/animals overseas;

• Delivering technology to agricultural industries faster

• Increasing incentive to commercialise technology in Australia

• Provisional review self-funded through sale of product

4. While there has been an APVMA pilot study, there is opportunity for implementation of third party APVMA approved certifiers rather than current APVMA monopoly;

• This approach has been implemented successfully in New Zealand

• The approach could be successfully implemented specifically for an industry led minor use program

• Would go some way in addressing the current critical shortage of regulatory expertise at the APVMA

5. Establish a points credit system for registrants who put minor use onto label being rewarded with acceleration of an alternate registrations evaluation priority to incentivise commercial investment in industry priorities where market failure exists. These credits could then be used to accelerate other applications being assessed perhaps even at a later time eg. 6-12 months later allowing the build up of credits;

• Would be a self-funding program by registrants

• Delivering minor use and new technology onto label to industry faster

• Encourages parity with international labels for agriculture

6. Adopt in new AgVet legislation and regulations improved data protection for emergency and minor use permits to improve the value proposition and incentive for commercial investment, encouraging contribution of exiting Australian and International data to these programs. In addition provide data protection incentives on existing registered labels encouraging investment in minor use through adopting a USA based system of 1 extra year for 3 minor use label extensions would;

• be self funding program by registrants

• potentially provide incentives for additional label registration of minor uses

• improve product stewardship through company label communication.

As detailed above, there are significant barriers to companies contributing protected data to minor and emergency use permits, particularly if this is new international data to Australia, which would not have already been protected through a label application process. The potential opportunity for increased data protection would provide incentive for greater investment by commercial manufacturers in minor use programs in Australia and this would also potentially support a longer-term objective of an increased number of permits being transferred to label registrations. Additional data protection incentives in the USA providing an additional 1 year of data protection for an additional 3 industry minor uses up to a maximum cap of 3 additional years has been a significant incentive to get minor use permits on to registered labels. Australia should consider adopting a similar scheme.
To address investment market failure in the longer term, there is need for transformational change to AgVet regulation in Australia. This should include consideration to full international co-regulation with a major technology development country. A transition to this could be supported through an interim provisional and/or conditional registration process. This will increase multinational confidence for investment into Australia and also increase Australia’s ranking on investment priority compared with competing investment opportunity in Asia and South America. This initiative would deliver:

- Consumer and government confidence in broader international standards
- Cost savings to Australia
- Fastest possible technology access for agricultural industries
- Ensuring Australia is on the first priority commercialisation list.

These options would capture not only minor uses but also major uses where there is demonstrated market failure for investment and a need for additional investment intervention. There is a need to expand the minor use definition to not only those things that are of low economic value to a registrant but also for situations where there is insufficient approved options for pest management or where investment market failure occurs impacting on industry productivity.

If Australia were to effectively collaborate with IR-4 in the USA, then there will need to be some government appropriation in an Australian equivalent. An investment model, which is at odds with the USA system, would be a significant disincentive for international collaboration with Australia. To address this there is a need to consider amendment to regulations so that no fee is payable (or is reduced to a certain %) if the use qualifies as a priority by written submission of the government nominated representative peak agricultural industry organisation or relevant research and development corporation defined under the PIERD Act.

There are significant advantages of having incentives in place as soon as possible to encourage industries to participate in priority setting process and additional industry and commercial investment. This includes the USA IR-4 approach of priority review by the USEPA for support of key industry priorities. Having these linked in the legislation, particularly in terms of fees and assessment timeframes would be an excellent initiative to deliver rapid benefits to industry and the community.

**GPA commitment to further reform discussion**

GPA is committed to further discussion with the Australian and state governments on the need to deliver transformational change delivering improved pesticide technology access and stewardship in the Australian agricultural industry. There is commitment from GPA to work cross industry and deliver productivity outcomes to agricultural industries and the Australian economy and community.

If you would like to discuss any of these comments and suggestions further in detail, please contact me on email andrew.weidemann@grainproducers.com.au or 0428 504 544.

Yours sincerely

Andrew Weidemann
Chairman GPA