19 July 2017

AgVet Chemicals Branch
Department of Agriculture and Water Resources
Via email: agvetreform@agriculture.gov.au

Re: Consultation on the AgVet Chemicals Legislation Amendment (Operational Efficiency) Bill 2017

The Hills Orchard Improvement Group (HOIG) is appreciative of the opportunity to provide a submission relating to the AgVet Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 and to comment on the associated ramifications for the primary food production industry within Australia.

HOIG is a self-funded and democratic organisation based within the $50 million Perth Hills production region of Western Australia and is free from the constraints of levy funding. The group represents over 70 businesses that produce a number of fresh fruit commodities including; stone fruits, pome fruits, avocados and persimmons to name but a few. HOIG’s membership also consists of a significant number of businesses that provide services to industry, such as wholesale, retail and secondary supply and merchandise products. As such these businesses also benefit from the strength, resilience and profitability of local producers.

HOIG recognises the value of an efficient and effective regulator in the Australian Pesticides and Veterinary Medicines Authority in providing a considered and sensible approach to the protection of human health via an assessment process that considers the safety of AgVet products for usage on primary produce bound for the supply chain.

HOIG also recognises that microbial resistance is an issue that is taken extremely seriously by primary food production industries.
HOIG is broadly supportive of the proposed legislative amendments and values the reductions in red-tape and transparency which will undoubtedly be of benefit to industry and producers.

However, HOIG has serious concerns with Proposal 8 and does not support the inclusion of this proposal for reasons which shall be documented.

The APVMA

HOIG considers the historical performance of the APVMA in providing a cost effective and efficient regulatory service as being inconsistent, confrontational and heavy handed which has taken Australia from a country that product manufacturers would have at the forefront to seek a permit application, to now being one of the last.

The registration process has moved from being extremely attractive in terms of cost, to being one of the most expensive in a global comparison.

HOIG has been informed by product manufacturers that there are examples of the product registration process taking up to 7 years, in which the APVMA’s outcomes provide for a permit with only a 1 day Waiting Period. This example of an ‘assessment time’ versus ‘product risk’ ratio is holding Australian producers back from being globally competitive.

It is little wonder that control products available to our producer members trail those available to global competitors by up to a decade.

HOIG has reviewed several APVMA assessments of products and permits, with the most notable being HOIG’s scientific challenge to the regulator’s recent attempted and then, after 3 further years, subsequent ban on a number of horticultural uses of fenthion. This 3 year period staved off financial ruin for many horticultural businesses by fruit fly decimation and provided industry with enough time for the APVMA to assess and provide permits for new chemistry which in turn provided the relief necessary for businesses to survive.

It must be noted that this 3 year lifeline was not provided without severe resistance from the APVMA despite the questionable deficiencies within the regulator’s original assessment.

In consideration of the current proposal 8 amendment, in conjunction with the APVMA’s previous conduct and track record, HOIG does not consider the APVMA an appropriate authority for this responsibility.

Concerns over Proposal 8

Proposal 8 seeks to include ‘microbial resistance’ to the list of considerations undertaken by the APVMA during a product registration/assessment process.

It is HOIG’s contention that the APVMA should not be granted this power for the reasons listed below.

- The control of microbes within the fresh food production model is achieved by a rotation of carefully timed and considered control applications from a number of products from differing ‘chemical groups’ as to avoid this very resistance outcome occurring. The establishment and structured nature of chemical groupings, based upon identification of
products containing similar molecular chemistry, is an important part of the registration process. It ensures that an over-reliance on any one chemical group does not occur and lead to resistance issues.

This scenario exemplifies the precise reason that the APVMA should not be granted the power to assess microbial resistance as part of the proposed legislative changes..

‘Microbe A’ on any given commodity can be controlled by products ‘X’, ‘Y’ and ‘Z’.

X, Y and Z are used by the producer on a rotational basis to control ‘Microbe A’ so that the microbe does not develop resistance to X, Y and Z.

If a producer was to use only product X as an exclusive control measure then that situation clearly has a greater chance of resulting in resistance by ‘Microbe A’.

The APVMA process only allows for the assessment of the applicant chemical in its own usage isolation, it not the applicant chemical used in conjunction with other control measures.

As such, product ‘X’ may very well in isolation provide resistance opportunities but the strategic usage of ‘X’, ‘Y’ and ‘Z’ mitigate this resistance factor.

Taking this argument to its logical extent, the APVMA removes the usage of product ‘X’ due to microbial resistance issues under the reassessment/registration process.

This now only leaves products ‘Y’ and ‘Z’ to control ‘Microbe A’, hereby creating an INCREASED chance of microbial resistance to a lesser number of available products, rather than a decrease in risk from a larger number of options.

In effect, the granting of the power of microbial resistance review to an organisation that only considers each control product ‘X’, ‘Y’ and ‘Z’ in isolation rather than the varied and targeted usage of the combined number of products is a short-sighted and dangerous proposition.

- The APVMA takes into consideration the number of products registered within any given chemical group so as not to create the scenario where a microbe is being controlled by a number of products with molecularly similar chemistry. The ideal scenario is to have a microbe controlled by varied products with differing molecular chemistry across a number of chemical groups. As such, the APVMA’s internal processes already contain a resistance prevention strategy.

- The addition of microbial resistance under the auspices of the APVMA will increase red-tape and the registration time unnecessarily. As shown in point 1 of HOIG’s concerns it is virtually worthless obstruction of efficient process in reviewing microbe resistance for a product in isolation and therefore this facet of assessment would provide no value, extend registration periods and increase costs.

In brief conclusion, it is HOIG’s contention that proposal 8 will in fact increase registration times, inefficiencies and costs and at the same time unnecessarily reduce the number of control options available for any given microbe.
A decrease in the number of control options will, in fact, lead to increased microbial resistance and a greater threat to industry, small businesses and importantly – the consumer.

The potential negative and destructive findings based upon APVMA assessments conducted upon individual products would be akin to if penicillin was isolated from the broader range of antibiotics and evaluated for future resistance development.

Would any sensible regulator reject or remove the usage of penicillin due to the fact it could lead to resistance issues in the future, if used constantly in isolation? The reasonable conclusion is ‘no’, as penicillin is used in conjunction with other anti-biotics, just as products are used in conjunction with complimentary products in primary food production for microbe control.

Thus, the clear conclusion is that the APVMA is not equipped or able to assess broader issues of microbial resistance in a practical and established microbe control program, as such Proposal 8 should be rejected.

For further comment/consultation, I can be contacted at XXXXXX@XXXXXXXX

Brett DelSimone

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