CropLife Australia Policy Statement on APVMA efficacy assessments

CropLife strongly supports retention of the Australian Pesticides and Veterinary Medicines Authority (APVMA) undertaking efficacy assessments to be satisfied with the suitability of agricultural chemical product label claims. Submitting efficacy and crop safety trials to the APVMA for assessment provides growers and the public confidence that the APVMA is addressing all scientific aspects of a product's registration. Reputable agricultural chemical companies conduct replicated efficacy trials to be satisfied in their own right that their product meets agronomic requirements and performs to commercial expectations. In the majority of instances the resulting data also satisfies APVMA requirements. Unfortunately, not all prospective applicants adopt the same level of integrity in the products they intend to introduce to the Australian market.

The cost of generating this data varies significantly depending on the number of targets, crops and the range of environmental conditions likely to be encountered. For a new chemical product seeking approved uses in a range of major crops, efficacy data development costs can be in excess of $400,000. However, bioequivalence data in support of a generic chemical product can be significantly less than $40,000. While the cost of undertaking this work may be considered high, these costs must be incurred by reputable companies as a matter of course and are therefore unlikely to be considered as a reason certain products are not introduced to the Australian market. Efficacy submission preparation costs are insignificant when compared with the field trial costs, and the field trial costs themselves are rarely the limiting factor with respect to timeframe and success of applications. This is particularly the case considering the evaluation of residue data has a longer APVMA assessment timeframe.

The majority of international jurisdictions with developed regulatory systems require registrants to prove the efficacy of their products before a product can be registered. Where efficacy is not required to be proven in the US before product registration, efficacy data must still be generated and held by the registrant and the regulator reserves the right to review the data as required. CropLife believes the current efficacy evaluation model provides a high level of protection for Australian farmers, gives a high level of consumer confidence that chosen products and rates are justified and necessary, and facilitates uniformity of claims and language between products while reducing litigation.

It is crucial that the data generated to satisfy APVMA efficacy assessments do not go beyond what is generated by respectable crop protection companies to understand their own products and have confidence in any label claims, as that would act as an inhibitor.

The single biggest impediment to innovative products being introduced into the Australian market is the size of that market. Removing efficacy assessment as a regulatory requirement will not change this fact. Removing APVMA efficacy assessments as a regulatory requirement or making it voluntary would, in effect provide less scrupulous companies easier access to the Australian market and significantly increase the risk of product failure for end-users. This outcome has a negative outcome for anyone involved in agriculture and as such, cannot be supported by CropLife.