Overview of Minor Use activities within Australia

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Introduction

The approval of safe and effective agricultural chemical products within all Australian agricultural sectors is a national issue, particularly for those minor users of agricultural chemicals whose use is not sufficiently economically attractive for a manufacturer to seek registration.

Before a chemical product can enter the Australian market, it must first be registered with the Australian Pesticides and Veterinary Medicines Authority (APVMA). Following registration, users of agricultural chemical products in Australia must comply with the control-of-use legislation that applies in their particular State. This legislation can vary between States, particularly with respect to what constitutes legal off-label use, but as a general rule only products registered by the APVMA can be used for labelled-use patterns. Product registration and new use patterns may only be submitted to the APVMA by the product registrant. To provide for 'minor uses' that do not attract commercial investment by registrants, users and affected industries may apply to the APVMA for consideration of a minor use permit to authorize an off-label use.

Five sectors represent the majority of minor use permit applications lodged, namely vegetables; fruit and tree nuts; non-crop situations; broad-acre crops; and forestry. Horticultural crops represent the vast majority of minor use permit applications at more than half of all applications. No central or single national minor use programme is established within Australia, although there is coordination of data generation and the making of regulatory submissions amongst a number of industries, most notably horticulture and grains via their respective research and development (R&D) arms.

There are approximately 900 current minor use permits issued by the APVMA. Copies of these permits may be obtained from the APVMA website at: http://www.apvma.gov.au/permits/search.php

User industry approaches to addressing needs

As noted above, users and affected industries may seek to have regulatory approvals granted for off-label uses that would otherwise be an offence, in the form of a minor use permit. Whilst no one central or single national minor use programme is established within Australia, the horticultural and grains industries through their respective R&D arms coordinate the necessary data generation and regulatory submissions for a large proportion of minor use permit applications lodged with APVMA.

Horticultural crops

Horticulture Australia Limited (HAL) operates the largest programme within Australia, and engages with its member industries to identify needs, prioritize projects, fund data generation (where necessary) and make regulatory submissions.

The HAL Minor Use Project regularly undertakes a Strategic Agrichemical Review Process (SARP). To date, fifty-four horticultural industries have conducted a SARP, with several more planned and some industries planning to update their SARP in 2012. The process aims to identify key minor use priorities by examining existing registrations and where a lack of suitable options exist to control key pests and diseases. The identification of new options for which industry would pursue minor use permits includes considerations of resistance management, their suitability for use in conjunction with Integrated Pest Management (IPM) and trade.

Since its inception in 1998, approximately AUS$ 7.2 million has been invested by HAL through the minor use programme, with approximately AUS$ 5.8 million of this by the vegetable industry. Annually, submissions to the APVMA from the HAL programme accounts for approximately half of all applications lodged by the horticulture sector, with other submissions lodged independently by individual growers or peak industry bodies at their own cost. In 2011 alone, the HAL minor use programme funded and commissioned AUS$ 1.4 million of minor use projects, making 140 minor use permit applications and having 122 minor use permits issued by APVMA.

Broad-acre grains (including minor cereals, oilseeds and pulses)

In addition to activities in the horticulture sector administered by HAL, the Grains Research and Development Corporation (GRDC) has also, for a number of years, run a "Pesticides for Minor Uses in Grain" programme that seeks to address minor use issues facing Australia's grain, oilseed and pulse industries. The programme engages with industry bodies such as Pulse Australia Ltd and the Australian Oilseeds Federation, and provides regulatory assistance to those organizations in the development and submission of minor use permits. Over the period 1998/1999 to 2009/2010, AUS$ 3.2 million (present value) has been invested in the grains minor use programme. Over half of the 25 grains crops covered by GRDC are classified as minor. Similar to horticulture above, a strategic review has been completed for 12 grain crops, examining existing pesticide options from the perspective of threats: resistance,

regulation, trade, etc. Minor grains, oilseeds and pulses comprise approximately 12 percent of all minor use submissions, and as with HAL, the programme does not administer all permits applied for by this sector.

Further details about the GRDC "Pesticides for Minor Uses in Grain" project may be found at: http://www.grdc.com.au/director/events/grdcpublications/minoruses.cfm

The legislative and regulatory landscape

'Minor use' is defined in legislation as

> *"a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose)"*

Further details regarding minor use criteria are explained in the APVMA Guidelines for Determining Minor Uses, available at http://www.apvma.gov.au/publications/guidelines/docs/minor_uses_guide.pdf

As outlined above, there are two principle regulatory mechanisms utilized for the approval of new uses, namely (1) product registration (approved on-label uses); and (2) minor use permits (approved off-label uses). The product registrant or permit applicant (as the case requires) must provide appropriate supporting information to the APVMA to demonstrate that the proposed chemical product and its use(s) will be safe and effective. Generally this requires the provision of scientific data on the product and proposed use(s) covering key areas such as toxicology, residues for both local and overseas markets, occupational health and safety, environment, efficacy and crop safety.

The APVMA will usually require locally replicated trial data supporting the proposed use in Australia. However, the APVMA will consider overseas or other data provided it can be demonstrated that the data are scientifically relevant to the proposed use in Australia. This is particularly relevant to the consideration of efficacy, crop safety and residue data provided in support of permits for minor uses.

Generally, minor use permit applications seek to use existing registered products in a manner similar to the currently approved use patterns of major crops. Therefore issues such as worker safety and environmental impact remain essentially unchanged and the APVMA can often rely on the existing risk assessments. This is often also the case for efficacy and crop safety requirements, where similarities with currently registered use pattern(s) can be demonstrated. As a result, the APVMA rarely requires detailed data for permit applications seeking to use currently registered products for related minor uses. A principle consideration for the APVMA is whether a suitable Maximum Residue Limit (MRL) can be established for the proposed use.

In establishing MRLs, the APVMA considers all available data, including overseas data if available and determined relevant. The APVMA in the consideration of Permits for minor uses regularly extrapolates residue data between like commodities, provided that the data is sound and a similar use pattern is being proposed. This often allows the APVMA to establish Temporary MRLs to enable Permits to be issued for interim periods whilst additional local supporting data is generated, usually over 2 to 3 years. The level of data requested reflects the minimum required for sound

decision making, while keeping regulatory costs for minor uses to a minimum. The APVMA has published guidelines outlining residue data requirements for new uses; a copy of this document is available at http://www.apvma.gov.au/residues/docs/residues_and_minor_crops_info.pdf

Further details on the process and requirements for minor use permits are available at http://www.apvma.gov.au/permits/agricultural/index.php

Reference sources

Minor Use of Agricultural and Veterinary Chemicals in Australia. Report of the OECD Pesticide Risk Reduction Group Seminar on Minor Uses and Pesticide Risk Reduction (see pages 26–33). http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono(2005)4&doclanguage=en

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