Australian Government

Australian Pesticides and Veterinary Medicines Authority

Procymidone proposed regulatory decision

Submissions received

October 2022

Chemical Review
APVMA
GPO Box 3262
SYDNEY NSW 2001

Date: 5th August 2022

RE: Procymidone – Proposed Review Decision

Horticulture Innovation Australia Limited (Hort Innovation) is a not-for-profit, grower-owned research and development corporation for Australia's $15.1 billion horticulture industry. Hort Innovation invests around $120 million in research, development and marketing program/projects annually to provide benefit to industry and the wider community.

Hort Innovation's key functions are to:

- provide leadership to, and promote the development of, the Australian horticulture sector
- increase the productivity, farm gate profitability and global competitiveness of the horticultural industries by investing grower levies and government funds in research, development, extension and marketing funds, program/projects services and providing information, services and products related to program/project outcomes
- promote the interests of horticultural industries overseas including the export of Australian horticultural products.

Hort Innovation welcomes the opportunity to provide a response to the APVMAs proposed regulatory decision for procymidone. Listed below are aspects identified for the APVMA's consideration.

Meeting the safety criteria - Spray drift restraints

Hort Innovation seeks further clarification regarding the application of buffer zones to livestock areas. A livestock area is defined as those areas where livestock are grazing. This suggests that the buffer zones indicated are relevant only in the event of livestock being present and grazing in the downwind area at the time of spraying. Is this correct, i.e., there are no restraints on livestock re-entry into a downwind area following completion of an application?

Meeting the labelling criteria – Product claims and use patterns

Hort Innovation wishes to flag some matters relating to Section 5D(1) of the Agvet Code, i.e., whether current labels contain adequate instructions. Firstly, under the *Critical Comments*[1] for some crop applications timings of procymidone, specific phenological growth stages are listed, e.g., for stone fruit starting at pink bud through flowering ceasing at shuck fall. It is suggested that the APVMA consider updating product labels to include BBCH crop growth stages[2], for improved clarity and consistency in identify application timings. Below is an example of the possible applications timings for stone fruit.

[1] See Directions for use as listed in Attachment C Proposed labels, to the Special Gazette of May 9th
[2] BBCH Scale: https://www.julius-kuehn.de/en/jki-publication-series/bbch-scale/

[redacted]

Apply at 10% blossom (BBCH 61), full bloom (BBCH 65), late petal fall (BBCH 69) and shuck fall (BBCH 72).
***DO NOT** apply after shuck fall.*
If weather conditions particularly favour blossom blight use higher rate.
NSW, SA, Qld, Tas and WA only. Where Monilinia laxa is known to occur apply an additional early spray at pink bud (BBCH 57).

A further label change Hort Innovation asks the APVMA to consider is requiring the inclusion of specific label text consistent with current resistance management guidelines on labels. For example, for Blossom blight (*Monilinia laxa*) and Brown rot (*M. fructicola*) in stone fruit the following text, or similar, could be added;

This use is subject to a CropLife fungicide resistance management strategy:

*"D**o not** apply more than two consecutive sprays of procymidone (or other Group 2 fungicide) before changing to another group, this includes the last application made in-field from one season to the next, i.e., the last Blossom Blight spray and the first pre-harvest brown rot spray should be regarded as consecutive applications."*

Finally, the jurisdictional status of approvals in a number of crops is unclear, i.e., are uses now All States and Territories? The Directions for use tables in the Special Gazette, do not display State columns[3]. Does this signify the APVMA no longer require the State and Territory divisions as previously listed on labels for wine grapes, stone fruit, onions, and garlic?

If this is not the case Hort Innovation would encourage the APVMA to consider doing so. For example, for Stone fruit, *Monilinia laxa* is known to occur within Western Australia and its omission from labels would seem unwarranted. Trane *et al.* (2017)[4] found that of 90 fungal isolates collected from *Prunus* species, exhibiting symptoms of disease, at 12 sites in stone fruit production areas in Western Australia 49 isolates belonged to *Monilinia laxa*, i.e., *M. laxa* is a relevant widespread disease in WA. As a result, it is believed appropriate that use in WA be included on product labels. It is suggested that other State and Territory gaps may be similarly unnecessary and no longer relevant.

Sincerely,

Jodie Pedrana
Regulatory Affairs – Crop Protection Manager

Horticulture Innovation Australia
[redacted]

[3] Attachment C Proposed labels, to the Special Gazette of May 9th

[4] Tran, T.T., Li, H., Nguyen, D.Q. *et al.* 2017. Spatial distribution of *Monilinia fructicola* and *M. laxa* in stone fruit production areas in Western Australia. *Australasian Plant Pathol.* 46, 339–349.

8 August 2022

Residues and Trade
Scientific Assessment and Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Response to call for public comment on APVMA Trade Advice Note and Request on

Procymidone proposed regulatory decision – May 2022

Thank you for the opportunity for Grains Research and Development Corporation (GRDC) to provide a response to the **Procymidone proposed regulatory decision as outlined in the Review Technical Report – May 2022.**

GRDC would like to make comment regarding the proposed deletion of the current MRL for VD 0523 Broad bean (dry) [faba bean (dry)] at T10 mg/kg and the current MRL for VD 0526 Common bean (dry) [navy bean (dry)] at T10 mg/kg.

It is noted that the findings of the review include that there was insufficient relevant residues data to determine an appropriate MRL for the currently registered use of procymidone on faba beans and its forage and fodder and that there was insufficient residues data relevant to the current Good Agricultural Practices (GAP) available for the support of the current MRL for navy bean.

GRDC proposes to undertake on behalf of the industry the required field residues studies, in support of the current GAP as per the existing product labels for the use of procymidone in both Faba bean and Navy bean to allow for the setting of a suitable MRL.

Based on the results provided by the National Residue Survey (NRS) GRDC believes that the continued use of procymidone by industry represents a minimum to nil risk to international trade when used in accordance with current label directions.

Published NRS data (https://www.agriculture.gov.au/agriculture-land/farm-food-drought/food/nrs/nrs-results-publications) for the past 10 years, has shown zero detached at ½ MRL to ≤ MRL of 10 mg/kg procymidone. Confidential data provided to Grain Producers Australia (GPA) by NRS, shows the actual detection levels of procymidone found by the NRS for the last 3 years of testing. This data can be found as part of the GPA submission to this review and it is GRDC's understanding that the levels of detection are below 0.1 mg/kg. GRDC believes that this data provides clear evidence that the current GAP on the procymidone label supports outcomes that are well below the current procymidone MRL for faba beans.

GRDC would welcome an opportunity to discuss further with the APVMA a process that would allow for the current registered claims to remain in effect, potentially via a permit, whilst the required residue data is generated. Such a process would enable the continued use of this important fungicide by industry.

Regards

Gordon Cumming

Manager – Chemical Regulations

[redacted]

About the Grains Research and Development Corporation

GRDC was established in 1990, under the then Primary Industries and Energy Research and Development Act 1989 (PIERD Act), as a transparent accountable entity to fund and administer the levy into RD&E to increase the profitability of the grains industry in Australia. As a result of amendments made in December 2013, that Act is now known as the Primary Industries Research and Development Act 1989 (PIRD Act).

The PIRD Act provides for the funding and administration of primary industries R&D to:

- increase the economic, environmental and social benefits to members of primary industries and to the community in general by improving the production, processing, storage, transport or marketing of the products of primary industries
- achieve sustainable use and management of natural resources
- make more effective use of the resources and skills of the community in general and the scientific community in particular
- support the development of scientific and technical capacity
- develop the adaptive capacity of primary producers
- improve accountability for expenditure on R&D activities in relation to primary industries.

The GRDC is principally supported by a grower levy and Australian Government contributions. The levy is based on the net farm gate value of the annual production of 25 crops: wheat; coarse grains—barley, oats, sorghum, maize, triticale, millets/panicums, cereal rye and canary seed; pulses—lupins, field peas, chickpeas, faba beans, vetch, peanuts, mung beans, navy beans, pigeon peas, cowpeas and lentils; and oilseeds—canola, sunflower, soybean, safflower and linseed.

GRDC's investment activities is administered under a Statutory Funding Agreement (SFA) between GRDC and the Commonwealth of Australia. A copy of the agreement is available on the GRDC website (www.grdc.com.au).

GRDC strategic purpose is:

To invest in Research, Development and Extension to create enduring profitability for Australian Grain Growers.

Australian grain growers aim to achieve sustainable profit by adopting the outputs of GRDC's investments in RD&E. The focus on enduring profitability is important to achieving the statutory objectives of GRDC's enabling legislation. It is only at the point at which a grain grower adopts the new technologies, tools and practices made available through GRDC's investment in RD&E that spill over benefits associated with this investment are realised. Some of the spill over benefits include:

- Improved economic and social outcomes in rural and regional communities.
- Improved environmental management underpinned by sound RD&E.
- Enhanced contribution to the broader Australian economy.

Operationally GRDC invests in RD&E portfolio that addresses profitability constraints and opportunities spanning temperate and tropical cereals, coarse grains, pulses and oilseeds. This involves coordinating and investing in RD&E initiatives; monitoring, evaluating and reporting on their impact; and facilitating the dissemination, adoption and commercialisation of their results.

GRDC invests approximately $1,000,000 annually in generating data for submission for registration, variation or permitted use of agricultural chemicals. This investment is done usually with a similar or greater investment with a registrant.

[redacted]

SUBMISSION

Procymidone review proposed regulatory decision

PO Box 370
Braidwood NSW 2662

9 August 2022

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Re: APVMA Procymidone review proposed regulatory decision

Thank you for the opportunity for Grain Producers Australia (GPA) to provide a response to the **APVMA Procymidone review proposed regulatory decision.**[1]

Background

There is a strategic need for fungicides for control of many crop diseases and procymidone has been a significant tool for grain producers for many years. This product is particularly important for control of a number of pulse and oilseed diseases. GPA in particular notes that procymidone provides protective and limited curative action for control of chocolate Spot (*Botrytis fabae*) in faba beans, as well as other diseases in canola, lentils and lupins. There is also a need for a range of modes of action to manage fungicide resistance. Chocolate spot commonly infects more than half of all faba bean crops in over 62.5% of production areas in Australia. Even with current use of fungicides, current losses are 14.4% and potentially over 45% in years suitable for disease development, even with current fungicide control measures including use of procymidone.[2]

GPA has reviewed the **APVMA Procymidone review proposed regulatory decision** and notes the recommendation to continue the current labels for canola, lentils and lupin (with additional Lupin harvest withholding period comment of - Not required when used as directed). GPA notes the recommendation for withdrawal of label use for Navy Bean seed due to insufficient residue data being submitted.

GPA also notes the APVMA review residue and trade summary of faba beans that no procymidone residues data for faba beans were submitted and does not recommend support for ongoing use of procymidone for use on faba beans as per the current label registration. GPA notes the review comments *"While residues data is available for other pulse crops such as dry bean and peas, lentils, navy beans and soybeans, the registered use pattern for faba beans differs significantly from the treatment regime employed in the trials. It is also noted that while there is a registered use for the pulse crop of lentils, faba beans and lentils are in different crop sub-groups*[3]*. There is insufficient relevant residues data to determine an appropriate MRL for the currently registered use of procymidone on faba beans and its forage and fodder. The continued use of procymidone on faba beans cannot be supported due to insufficient residues data. The current MRL for VD 0523 Broad bean (dry) [faba bean (dry)] at T10 mg/kg should be deleted."*

GPA <u>does not support the approach the APVMA has used</u> or regulatory decision applied in the determination of crop residue groupings applied in the case of the Procymidone review proposed regulatory decision.

While procymidone has been registered for use on faba beans since 1998, the review report suggests there appears to be an MRL data gap for faba beans. Registration for use on faba beans has previously been included by the APVMA under the pulse crop grouping. The faba bean crop **Subgroup 015A, Dry beans** appears to have been unfortunately singled out following the APVMA refinement of crop groupings in 2019, even though the initial call for additional residue data as part of the review was back in 2005, well before this change.

In addition, GPA submits the attached residue data in the following Table 1 [redacted]

[redacted]

[1] https://apvma.gov.au/node/100291
[2] https://grdc.com.au/~/media/documents/resources/publications/grdcreportdiseasecostpulsespdf.pdf
[3] Australian Pesticides and Veterinary Medicines Authority, *APVMA crop group list for pulses*, accessed 15 October 2021.
[4] https://www.agriculture.gov.au/agriculture-land/farm-food-drought/food/nrs/nrs-results-publications

[redacted] This data provides clear evidence that the current Good Agricultural Practice (GAP) on the procymidone label supports outcomes that are well below the current procymidone MRL for faba beans.

GPA asks the APVMA to reconsider the determination for use of procymidone for use on faba beans based on previous regulatory determination of inclusion of residue data under the **Crop Group 015: Pulses.** Due to the misalignment of the procymidone review data request dates and changes to crop groupings dates, a meeting with the APVMA is requested to discuss the industry implications and resolution options resulting from misalignment of these date changes, plus consideration of the supporting NRS procymidone residue data presented.

If you would like to discuss any of these comments and suggestions further in detail, please contact me on email [redacted] or mobile [redacted]

Yours sincerely

Colin Bettles

Chief Executive
Grain Producers Australia
[redacted]

Background on GPA

Grain Producers Australia (GPA) represents the interests of an estimated 23,000 grain producers who grow broadacre, grain, pulse and oilseed crops throughout Australia, contributing to the economic strength of their communities, and an industry valued at an estimated $13 billion.

GPA advocates national policy outcomes with benefits for grain producers and to deliver a more profitable, sustainable and globally competitive Australian grains industry.

As a not-for-profit company limited by guarantee, GPA is governed by a board that's elected by producer members, representing the major grain producing regions. GPA's membership comprises direct producer members and producer members of the Grains Councils of State Farming Organisations. The elected leaders of these groups – backed by professional staff – also represent their members' interests, via the GPA Policy Council.

GPA's State Members include:

- Agforce Grains
- Grain Producers SA
- NSW Farmers Association
- Victorian Farmers' Federation Grains Group
- Tasmanian Farmers and Graziers Association
- WAFarmers Grains Council
- WA Grains Group

This robust representative process also engages and enables producers to advocate their views and deliver policy outcomes via various GPA Sub-Committees and Taskforces; such as the GPA Biosecurity Committee and GPA Pesticides and Technology Sub-Committee.

GPA's objectives are to:

- Provide 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.
- Facilitate a strategic approach to research, development and extension intended to deliver sound commercial outcomes from industry research.

GPA also has important responsibilities representing the interests of Australia's 23,000 levy-paying grain producers under federal legislation.

This includes; managing biosecurity for the Australian grains industry through Plant Health Australia as a signatory to the Emergency Pest Plant Response Deed (EPPRD); as a joint Representative Organisation responsible for overseeing the Grains Research and Development Corporation's performance and strategic investment, with matching Federal Government funding, in RD&E activities, under the PIRD Act; and managing the risk of chemical residues and environmental contaminants in grain products, to help facilitate access to domestic and export markets and protect product integrity and export reputation, via the National Residue Survey.

Grain growers contribute 1.02 per cent of their net crop sales toward levies comprising the GRDC the EPPRD responsibilities, Plant Health Australia membership, National Residue Survey testing. Of that, the vast majority (0.99pc) goes to the GRDC, with PHA receiving 0.01pc, the NRS 0.015pc and emergency plant protection response the remaining 0.005pc.

According to the latest report (Report to levies stakeholders 2018–19, Appendix B) grower levies to GRDC (97% of levies paid by grain growers) were at least $110 million for each of the 5 years reported. The average between 2014-15 and 2018-19 of grower levies to GRDC was about $120m, ranging from $100m to $139m. The corresponding average paid to all bodies is about $124m.

Further information: https://www.grainproducers.com.au/