Australian Government

Australian Pesticides and Veterinary Medicines Authority

Update to guidelines for determining a minor use

Submissions received

July 2023

Animal Medicines Australia
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29 June 2023

Director, Permits and Minor Use
Australian Pesticides and Veterinary Medicines Authority (APVMA)
By email only: enquiries@apvma.gov.au

Dear Director,

Re: Update to guidelines for determining a minor use

Thank you for the opportunity to provide initial comments on the guidelines for determining a minor use.

Animal Medicines Australia (AMA) is the peak industry body representing the Australia's leading animal health companies. Our members are the innovators, manufacturers, formulators, and registrants of a broad range of veterinary medicines that protect and treat animal illnesses, diseases and injuries, and support animal welfare, across the livestock, equine and companion animal sectors. AMA members represent more than 90% of Australian sales of registered veterinary medicinal products.

AMA supports mechanisms that provide greater access to products where there is a limited market, an infrequent or sporadic need for use, and/or where there are limited or no products available for an important therapeutic need. The use of veterinary medicines in these situations may not provide sufficient economic returns to support a product registration, yet is essential to deliver important animal health and welfare benefits.

The current guidelines are intended to assist applicants in determining whether a particular use can be defined as a minor use through criteria set out in 3 schedules:

- Schedule 1 identifies 'major species' where any species *not* on this list would be considered a 'minor' species.
- Schedule 2 identifies circumstances that represent minor uses in major species.
- Schedule 3 subjectively evaluates the potential economic return of a proposed veterinary chemical use. The applicant must demonstrate that there would be insufficient economic return to consider registration of the product and/or use.

If an application meets the criteria set out in one or more of these schedules, then it satisfies the definition of a 'minor use'.

This consultation is focused on updating the guidelines to reflect changes in the agricultural sector since the guidelines were first developed. The consultation documents do not identify any particular problems or concerns with the current schedules with respect to animal health.

AMA has not identified any specific problems with the schedules from the animal health perspective. In the absence of identified issues or problems that require attention, AMA considers that no changes are needed to the current schedules used to determine minor uses for animal health.

The current guidance material is heavily focussed on agricultural applications. However veterinary medicines are used in different ways and for different reasons to agricultural products, such that the criteria to determine minor uses in one sector are not necessarily applicable to the other sector. Minor uses to address animal health and welfare needs may be more effectively supported through veterinary-specific guidance material and AMA would be pleased to assist with this work.

Greater clarity on data requirements in Schedule 3 would be welcomed, especially where there are limited data available to support evaluation under Schedule 3. For example, there are four information types listed under 'investment costs' and four different information types under 'return on investment'[1], but no guidance how much data is required to be considered 'sufficient' by APVMA. More detailed guidance would assist applicants in preparing applications and would support the efficiency of APVMA assessments to provide timely access to minor use permits.

Incentives for registering minor uses could take inspiration from the human pharmaceutical framework for 'orphan drugs'. Orphan drugs (used to treat rare diseases or disorders where the disease affects fewer than 5 people per 10,000 when the application is made) have a limited market and are therefore less likely to be registered by pharmaceutical companies. Fee waivers for registration can be applied if a medicine is designated an orphan drug.[2] A similar framework for minor uses could encourage the registration of products that meet unmet needs, or needs that may be only partially satisfied by the products currently available.

In summary:

AMA supports the provision of guidelines that provide applicants with a simple and practical method to determine a minor use for veterinary chemical products. Where there are important animal health and welfare outcomes achievable in circumstances where no viable commercial opportunity is likely, then the minor use permit system should have adequate flexibility to bring that innovation to market, irrespective of the species. Specific guidance for animal health minor uses may support better utilisation of the minor use system to meet animal health and welfare needs.

If we can provide any further information, please do not hesitate to contact me. AMA looks forward to further consultation when the draft updated guidelines are available.

Yours sincerely,

[redacted]

[1] https://apvma.gov.au/node/10931
[2] https://www.legislation.gov.au/Details/F2023C00011

15 June 2023

Director, Permits and Minor Use
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

BY EMAIL ONLY: enquiries@apvma.gov.au

To whom it may concern,

The Australian Mushroom Growers' Association (AMGA) is the peak-industry-body who has represented the Australian mushroom growers for 62-years. AMGA works with all parts of the supply chain, from production through to the consumer. Our members are predominantly (but not exclusively) growers *Agaricus Bisporus*, the common white button mushroom, flats, swiss brown and portobello variety. Majority (95%) of the mushrooms consumed in Australia are *A. Bisporus.*

AMGA believe Mushrooms are a Minor Use crop, yet they are currently classified as being major. We would like to be a part of this APVMA minor use review process, as we do not believe that the proposed parameters adequately evaluate and classify our unique industry.

Mushrooms are currently categorized in the guidelines under *'Fruiting vegetables – other than cucurbits.'* Please note that mushrooms are not a vegetable, they are fungi, and belong to an entirely different biological category to plants[1].

The Australian Mushroom industry produced 66,236 tonnes of mushrooms in 2022[2], with a farm gate value of $434.2M. While considered a relatively high value crop, it needs to be noted that there are **only 42 growers** of Agaricus Bisporus nationwide, with majority of production via farms located in the southern states, Victoria (37%), NSW (31%) and SA (17%) with a few smaller farms in QLD (6%) and only one farm in WA (9%)[2]. Due to recent pressures of rising cost of production and difficulty securing reliable labor, farm numbers are currently declining. **Crop value is not a good assessment criterion to determine whether a crop is major or minor. The AMGA believe mushrooms should be considered minor, due to the extremely low number of growers.**

Mushrooms are grown in purpose built insulated, air-conditioned structures with growing beds stacked 6m high, therefore the land area of a mushroom farm is very small in comparison to other commodities like carrots or potatoes. **As mushrooms use little land (132ha[2]), under the proposed guidelines, mushrooms should be considered a minor crop.**

The Australian mushroom industry have very low exports, with just 69 tonnes of mushrooms exported in 2022[2] It must be noted that the figures in the Australian Horticulture Statistics Handbook 2021-22 include all varieties of mushrooms, and these export figures are reflective of exotic mushroom varieties (e.g. Morals and Shiitake) with almost no A.Bisporus exports.

I have asked the mushroom industry Pest and Disease experts, Dr Warrick Gill and Judy Allan to provide their top-level feedback on the guidelines. Dr Gill has provided a table (see 'schedule 1' in appendix) and their collective comments are summarised below:

- Legal access to pesticides is an important component of the Integrated Pest and Disease Management of pests and diseases in the mushroom industry. Most new chemistry and modified use patterns that has been introduced into the mushroom industry in the past 10-15 years has been via APVMA's Permit system so it could be said that there is already an acceptance that Mushrooms is a minor crop because it is not commercially viable for chemical companies to invest in generating data and pursuing registration for mushrooms and therefore, we work closely with Hort Innovation to gain access for pesticides for mushroom growers.

- Gaining access to approved chemicals is becoming increasingly difficult for the mushroom industry, due to the unique nature of fungi and costs involved in new product registration are excessive and cannot be recouped through sales to the mushroom industry alone.
-
    - recent communications with Scott Taverner demonstrate this very well – two sanitizing products tailored specifically for use in the mushroom industry have been developed, tested and demonstrated to be effective beyond other sanitizing products available yet the manufacturer cannot afford registration renewal fees
    - with only 42 growers nationwide, industry cannot support a new registrant to supply a range of products encompassing diverse activities to allow product rotation and effective resistance management
    - due to the unique nature of the cropping cycles, application of products to mushroom crops is determined by withholding periods – does this affect minor crop status?

- Mushrooms is a relatively high value crop produced by a small number of growers

- Sweet corn is not listed in 'schedule 1' so is therefore considered a minor crop yet production exceeded that of mushrooms, although production value is much less
    - production volume = 74,685 tonnes in 2022
    - production value = $149.8m in 2022
    - per capita consumption = 1.32kg

- Cucumbers are not listed in 'schedule 1' so is therefore considered a minor crop yet production exceeded that of mushrooms in both volume and value
    - production volume = 88,429 tonnes
    - production value = $229.9m
    - per capita consumption = 3.2kg
    - Cucumber (minor crop) production volume and production value figures exceed those of several major crops

Questions:

- What are the criteria that APVMA apply to determine minor status?

- **What does the APVMA consider as 'mushrooms'?**
    - *Agaricus* only?
    - *Agaricus* and exotic varieties including oyster, Shiitake, shimeji etc as Hort Innovation does?
    - The Hort VegeStats report includes all mushroom varieties

The AMGA would welcome the opportunity to do a presentation to APVMA about the structure of the mushroom industry, cultivation techniques and industry practices to assist their decision making process to determine that Mushrooms should be classified a Minor Crop .

Yours sincerely,

Leah Bramich
Relationship and General Manager
Australian Mushroom Growers Assoc.

cc. Nick Femia, AMGA Chairman

References

1. Naranjo-Ortiz et al. Biol Rev Camb Philos Soc. 2019;94(6):2101-37
2. Australian Horticulture Statistics Handbook for 2020/21

Major / minor vegetable crop production figures compared (according to APVMA 'Schedule 1') from latest Hort VegeStats publication

Crop status Major Minor	Production volume (tonnes)	Production value ($m)	Fresh export volume (tonnes)	Fresh export value ($m)	Per capita consumption (kg)
Artichoke	446	1.2	8	<0.1	0.02
Asparagus	7.368	77.9	1,180	10	0.34
Beans	28,169	134.4	1,188	6.2	1.06
Beetroot	14,659	13.8	346	1.3	0.22
Broccoli	71,786	289.9	1,648	8.4	2.57
Brussels sprouts	5,353	27.5	298	1.8	0.16
Cabbage	65,116	49.3	364	1.2	2.11
Capsicum	71,383	211.8	360	1.5	2.61
Carrots	306,394	247.9	99,247	92.2	7.26
Cauliflower	76,943	60.7	225	0.9	2.71
Celery	58,291	65.2	4,221	7.7	2.05
Chillies	2,242	12.2	4	<0.1	0.07
Cucumber	88,429	229.9	79	0.6	3.22
Eggplant	8,270	21.7	9	<0.1	0.3
English spinach/silverbeet/kale	6,715	23.5	322	2.7	0.23
Fennel	1,385	4.0	—	—	0.05
Garlic	3,173	20.9	—	—	0.44
Ginger	4,495	25.8	55	0.5	0.09
Lettuce (head)	134,726	266.7	413	1.2	5.18
Leeks	10,722	34.1	126	0.8	0.41
Mushrooms	**66,236**	**434.2**	**69**	**5.1**	**2.57**
Onions	266,429	248.7	42,305	33.9	7.8
Parsnips	3,579	14.2	—	—	0.13
Peas	31,122	70.1	6	<0.1	0.27
Potatoes	1,462,065	830.2	45,661	36.2	17.01
Pumpkins	112,895	106.5	2,628	3.8	4.11
Sweet corn	74,685	149.8	—	—	1.32
Sweet potato	102,754	73.9	1,170	2.3	3.61
Tomatoes	436,907	645.1	1,036	5.5	8.24
Zucchini	38,849	80.0	—	—	1.46

15th June 2023

Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

RE: Review of guidelines for determining a minor use- Re-categorisation of Sunflower to a Minor Crop

In considering the existing Guidelines for determining a minor use, the Australian Oilseeds Federation (AOF) is of the firm opnion that the current classification of sunflowers should be changed to that of a **minor crop**.

The area planted to sunflowers is small and can vary significantly from year to year. The crop is primarily grown in NSW and Qld with Northern New South Wales, Southern Queensland and Central Queensland the main locations. The area planted and volume of production is low with ABARE recently estimating the area planted in 2021/22 at 19,400 ha with a low of 8,500 ha in 2019-20. The 10 year average of area planted was 18,600 ha, and for the volume of production of 24.1 kt. i.e., 2012-13 to 2021-22[1], small when compared to canola at 3.9 million hectares and 8,273 kt.

In terms of value, the national crop was estimated at $13.7 mio in 2020[1]. Little of the crop is exported with the bulk of domestic requirements for sunflower kernels for the equine and birdseen market.

In accordance with the existing guidlelines, (volume of commodity production; area under cultivation (ha); dietary consumption (g/kg BW/day); value of crop or animal; and export quantities, the AOF therefore recommends that sunflowers should be considered a minor crop and proposes that the APVMA amends the categorisation accordingly.

Yours sincerely,

Nick Goddard
CEO- Australian Oilseeds Federation Inc.

[1] ABARES 2020, Agricultural commodities: December quarter 2020, Australian Bureau of Agricultural and Resource Economics and Sciences, Canberra, December. CC BY 4.0. https://doi.org/10.25814/vtqw-gm4

Guidelines for determining a minor use - APVMA consultation

Submission of the
Australian Veterinary Association Ltd

15 June 2023

www.ava.com.au

The Australian Veterinary Association (AVA)

The Australian Veterinary Association (AVA) is the national organisation representing veterinarians in Australia. Our members come from all fields within the veterinary profession. Clinical practitioners work with companion animals, horses, livestock and wildlife. Government veterinarians work with our animal health, public health and quarantine systems while other members work in industry, research and teaching. Veterinary students are also members of the Association.

Guidelines for determining a minor use - APVMA consultation.

Submission from the Australian Veterinary Association.

Background

The APVMA has requested stakeholder input in relation to the guidelines for determining a minor use.

Minor use permits are issued to allow for the legal use of AgVet chemicals in situations where registration of the product would not produce sufficient economic return. A minor use may include use on a minor crop, animal or non-crop situation, or limited use on a major crop, animal or situation.

Issues

Definition of 'Minor Use'

The minor use guidelines are heavily targeted to the agricultural sector rather than the veterinary sector.

The current guidelines are principally related to agricultural usage with extensive lists of various crop species. There is a list of major animal species and discussion that if the use is in a non-major species or the treatment is in less than 10% of the number of animals, it can be classified as a 'minor use'.

It can be very difficult to assess animal disease incidence in Australia as there are very few national requirements for disease reporting, apart from for notifiable diseases, and thus it is difficult to confirm a disease incidence of less than 10%.

There are many more current agricultural permits compared to veterinary permits; on the APVMA website permit search function there are almost 1000 current agricultural permits and only around 120 current veterinary permits.

The need for 'Supply Permits' or similar

In the past there was the possibility for a 'supply permit' for Veterinary products as part of the 'minor use' permit system. These permits covered supply during the registration process, which often takes 3-5 years. This was a very useful type of permit for low value, schedule 4 veterinary medicines for companion animals, including horses.

There is an increasing use of compounded veterinary medicines, which require no registration, and at the same time, an increasing regulatory burden for registration of products. The APVMA is moving towards being equivalent to International Regulatory Authorities, such as the CVM (FDA) and the EMA, with resultant higher requirements for quality, efficacy and safety studies, and an associated much higher regulatory cost and longer assessment times. As such it is difficult for veterinary pharmaceutical companies to justify the registration costs when veterinarians can compound an identical product to a registered product.

If a supply permit can be issued for these low value products this would allow sales and income revenue during the lengthy registration process.

Currently there is very little incentive for registration of such products and Australian veterinarians are missing out on being able to use registered products and are relying on compounded products, which have no requirement for proof of efficacy, safety or stability, these products should ideally be niche products for situations where there is no suitable registered product (due to species, formulation, route of administration etc), however they are becoming first line treatments for many species and many diseases.

In addition, the Australian market is very small in comparison with the US and EU markets, and it is difficult for pharmaceutical companies to justify the registration costs and timeframes for a registration in Australia. Typically, these products have already been approved by an overseas regulatory authority and yet the information needs to be re-assessed by the APVMA, with resultant increased costs and delays.

If a supply permit could be issued for innovative or novel products this would allow sales and income revenue during the lengthy registration process and make the registration of these products more appealing.

Similar to the situation for low value products, there is little incentive for registration for some innovative products which are approved overseas resulting in lack of access to these products for Australian veterinarians.

The AVA recommends that the guidelines for 'minor use' should be expanded to include 'supply permits' and include Schedule 4 Veterinary Medicines, for supply only to registered veterinarians for companion animals, including horses.

The products could not include anthelmintics, nor antimicrobials if there are different sensitivity patterns for Australia compared with countries where the products are approved.

The products would need to be novel, either by active or route of administration and not similar to any existing registered product.

The requirements for approval of the permit should be reduced so that these permits can be approved rapidly with a minimum data requirement of, for example -

GMP manufacture

- Reduced shelf life based on minimum of 6m accelerated data.
- Scientific argument supporting efficacy and safety with a commitment to full registration. The APVMA could request a statement such as 'The efficacy and safety of this product has not been approved by the APVMA.'
- Relevant human safety statements as per overseas approval if unscheduled with a commitment to scheduling as part of full registration.

AVA Contact:

Dr Melanie Latter
National Manager, Policy and Veterinary Science
E: melanie.latter@ava.com.au

[redacted]

[redacted]

[redacted]

[redacted]

Review of guidelines for determining a minor use

Dear Sir/Madam

Thank you for the opportunity to provide feedback on the minor use guidelines. The AgVet Code Regulations 1995 define a minor use:

> *#1. in relation to a chemical product or an active constituent, is 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).*

> *#2. in relation to a chemical product, is a use of the product where the following apply:*

(a) instructions for that use are in the Register in relation to one or more registered chemical products;

(b) none of those registered chemical products is available for sale anywhere in Australia.

While APVMA is revising the guidelines regarding #1 (insufficient economic return), it would be appreciated to include guidance on how to apply for minor use under #2 for veterinary products. Currently, such information cannot be found on the APVMA website. It is not clear if #1 and #2 are options i.e. one can apply either #1 or #2. Or when there is a registered product, #1 does not apply and one must look to #2. Also if a product is approved under #2, what will happen to the permit when the registered product resumed supply in Australia?

Please find attached the public submission cover sheet.

Kind regards

Sarah

Sarah Lam

Group Regulatory and Government Affairs Manager

Bioproperties

[redacted]

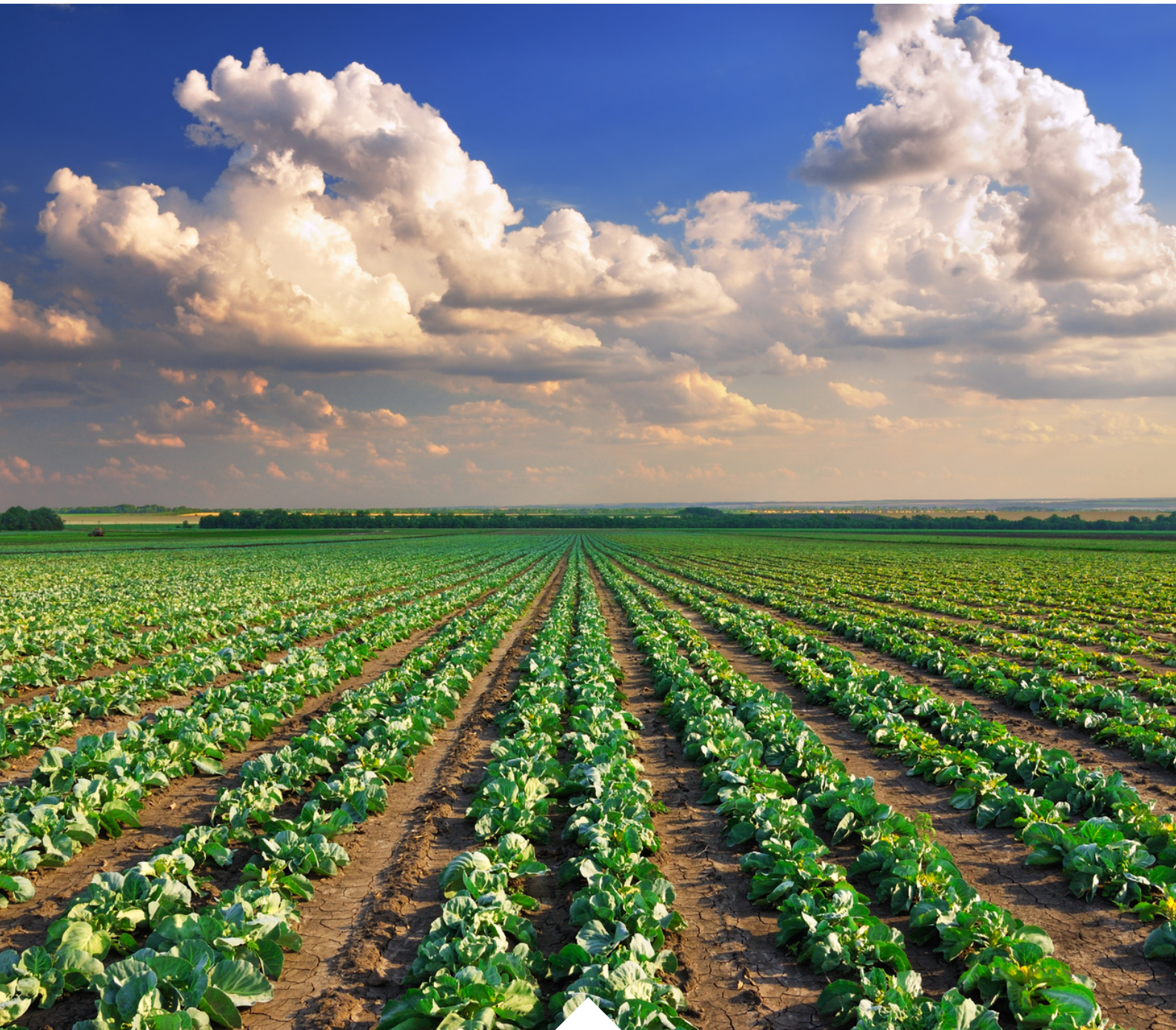
[redacted]

CropLife Australia

June
2023

Updating the guide for determining a minor use

Discussion paper



1. INTRODUCTION

CropLife Australia is the national peak industry organisation representing the agricultural chemical and plant biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of crop protection (organic, synthetic and biologically based) products and crop biotechnology innovations. CropLife's membership is made up of both large and small, patent holding and generic, and Australian and international companies. Accordingly, CropLife only advocates for policy positions that deliver whole of industry benefit. The plant science industry provides products to protect both crops and Australia's precious natural environment against damaging insects, invasive weeds and diseases that pose a serious threat to the nation's agricultural productivity, sustainability, food security and our beautiful national parks, nature reserves and delicate biodiversity.

The plant science industry delivers more than $20 billion in agricultural production annually to the Australian economy and employs thousands of people across the country[1].

CropLife welcomes the opportunity to provide comments to the discussion paper for *Updating the guide for determining a minor use*. Considering the dynamic nature of the agricultural landscape, it is crucial to adapt to the evolving market conditions. Despite Australia's producers growing similar crops and facing similar pest and disease challenges to producers in other countries, the Australian crop protection market is less than five per cent of the Global Market compared to other OECD markets such as the US and EU, which are around seven times larger[2].

1 https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf
2 Deloitte (2019) Agvet Chemicals – Market Drivers and Barriers

2. ADDRESSING THE MINOR USE PROPOSAL

CropLife acknowledges the need for revisiting the existing guidelines, which were initially formulated in the early 2000s. As the agricultural landscape has undergone significant changes since then, it is essential to ensure that the classification of major and minor uses of pesticides accurately reflects the current market dynamics. Crops that were once considered major may now have a diminished market share, while previously minor crops may have experienced substantial growth in popularity or value.

The minor use and minor crops system plays a pivotal role in promoting sustainable agriculture and environmental stewardship. By recognizing the unique pest challenges faced by minor crops, the process encourages the development and registration of targeted, lower-risk pesticides specifically tailored to these crops. This approach minimizes overall pesticide usage, enables innovation in otherwise commercially unrealistic applications, and reduces the risk of pesticide resistance.

The case study by the APVMA regarding the inclusion of certain crops under Schedule 1 - Major crops, animals, or non-crop situations, highlights the necessity for an updated classification system. Additionally, CropLife agrees that the economic viability of certain uses may not meet the criteria for a "major" commodity but would not fall under the "limited use" criteria outlined in Schedule 2.

CropLife supports the development of a well-defined set of parameters to classify major and minor uses.

The proposal to develop a tool or framework to reassess and review the list of major commodities is therefore welcomed by CropLife, as this is a gap in the current system. The United States of America definition automatically includes all crops under 300,000ac. While this number would clearly capture the majority of the horticultural crops grown in Australia, establishing a numeric threshold (area under production or numbers of trees or animals) would provide a reliable, predictable cutoff point for definitive purposes.

Planted area may fluctuate from year to year, following weather trends. Care must therefore be taken when adding or removing crops from Schedule 1, given the commercial realities and resource constraints associated with generating the necessary data for minor use crops or pests. CropLife suggests implementing a minimum five-year phase-out period, whereby any additions to the Schedule 1 list be notified for a period of not less than five years. This timeframe would provide stakeholders with adequate time to complete the requisite studies and ensure compliance with registration requirements.

A key indicator of the Economic Return test under Schedule 3 should likewise provide indication into crops or pests which have poor rates of return. Therefore a comparative review of registrations of crop protection products available to Australian farmers' overseas competitors would support the economic return definitions embedded in legislation. The market failure demonstrated by this regulatory cost-induced differential in available crop protection products for identical crops will help further inform the classifications of major v minor crops. It could be noted at this point that this should be core work of the Agvet Policy branch of the Department of Agriculture, Fisheries, and Forestry.

In further refining the Schedule 1 guidance, the value of the crop (or animal) could be taken into consideration. However, as has been demonstrated over the past several years, short transient global effects may inflate the value of a hitherto minor crop onto the Major Crops list. Care should be taken to ensure that short term fluctuation in crop value does not eliminate a minor crop, and further exacerbate the limited pest control options.

The availability or utilisation of incentives to generate interest in pursuing registrations for minor crops, however, should not be included in the review of Schedule 1. Excluding incentives such as crop grouping and extended data protection periods from the guidance for determining a minor crop is crucial to maintain a fair and balanced regulatory framework. Crop grouping, for instance, involves categorising crops together based on similarities in their growth habits or uses. This approach can potentially overlook the unique pest management challenges faced by individual crops within a group.

Similarly extended data protection or limitation on data use periods, which incentivise the registration of new and novel pesticides for minor uses, should not impact the crop or pests' status. While it is undesirable to have no crop protection options for a minor crop, it is only a slight improvement to have very few choices in crop protection. It is crucial for both integrated pest management and pest resistance stewardship to have a wide array of products and modes of action for pest control. Allowing the existence of these incentives to affect the status of a minor crop or use would compound the lack of choice in crop protection products, and stymie integrated pest management practices.

The guidance laid out for Schedule 2 – Limited use within a major crop, animal or non-crop situation and Schedule 3 are already clear. These guidelines facilitate utilisation of the most current data to aid registrants in making a case to test the economic viability of the introduction of a novel pesticide for the given crop or pest. In consideration of the updated guidance, however, the APVMA should note that data provided in support of a Schedule 3 claim are confidential commercial information. Clarity and assurance should be made both in the guidance and internal procedures to ensure that these data remain confidential.

CropLife suggests at this point it would be an opportune time to address the shortcomings in the Legislative Instrument *Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2022*[3]. More clarity or refinement is needed on the current process: the potential for additional data protection is an incentive for registering minor uses and further improvements in this area are welcome, however they must be logical with a clear and easy to follow process. During the "consultation" with the then Department of Agriculture, Water and Environment (DAWE, now the Department of Agriculture, Fisheries and Forestry – DAFF), CropLife raised several questions and concerns with the application of the Legislative Instrument, which were largely ignored. The attached submission made to the Department will illustrate them adequately. As a result, while CropLife member companies have been investing in addressing the priority pests and crops, the legislative instrument remains murky and unnecessarily complicated with many unanswered questions.

Likewise, as part of addressing the minor use problem, more should be done to affect permit-to-label transition. While DAFF has provided a grant of $240 000 to the APVMA to examine all permits currently issued to peak industry bodies and determine suitable candidates for migration from APVMA permit to full product registration, this process has been slow and arduous.

There are approximately 1200 current minor use permits issued by the APVMA and it is understood that approximately 75 per cent of these account for uses in horticultural crops (60 per cent) and grains (15 per cent) respectively, or close to 900 permits currently servicing these agricultural industries. Permits are not permanent and are frequently issued for periods ranging from 2-5 years. Permits require ongoing administration and renewal, at cost to both agricultural industries who hold these permits and the APVMA in processing and assessing renewal applications.

[3] https://www.legislation.gov.au/Details/F2022L00166

3. CONCLUSION

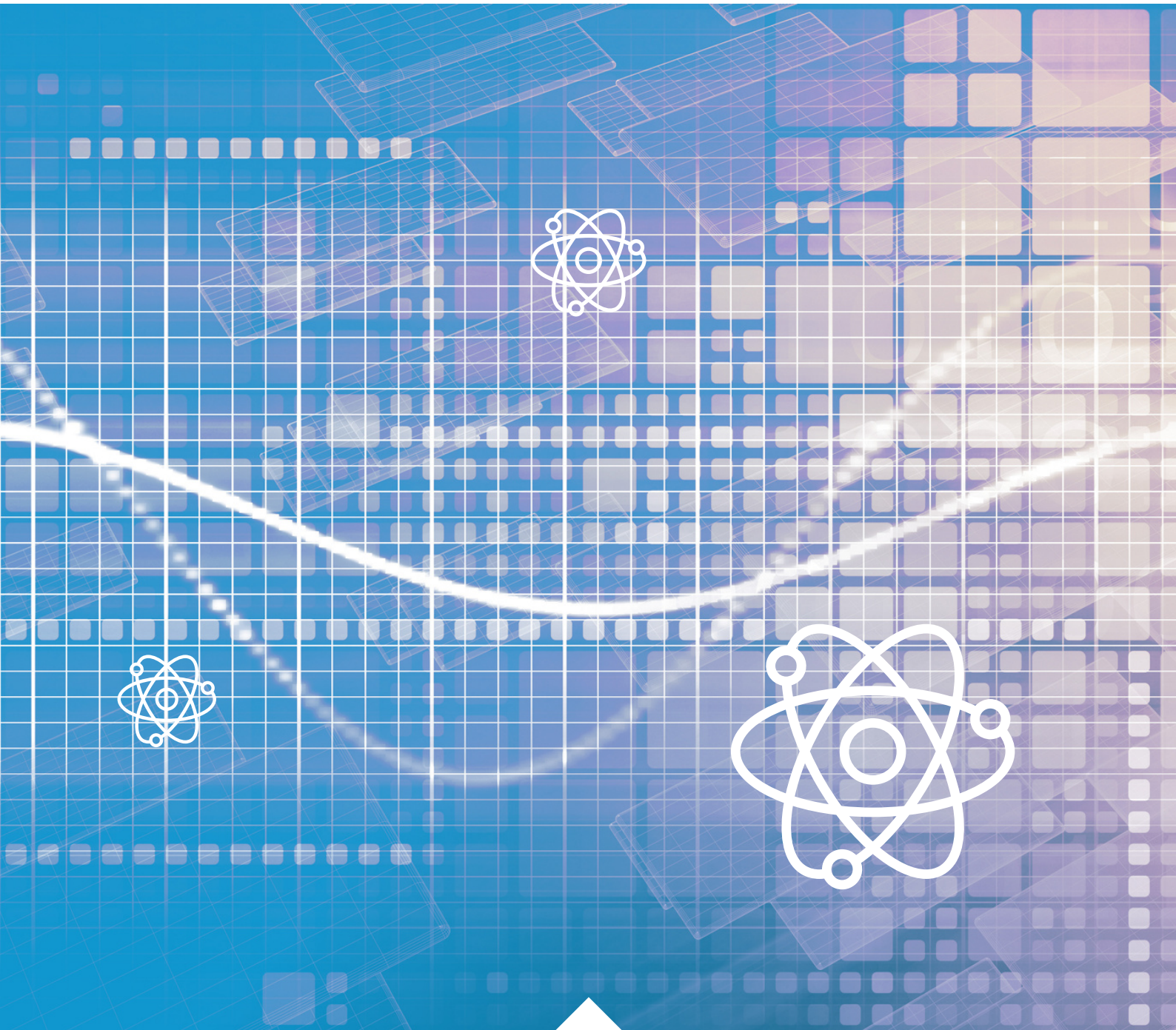
CropLife is pleased that the APVMA is committed to modernising and improving the minor uses guidelines. Australia's farmers are at a disadvantage due to registration and regulatory hurdles and expenses when it comes to the availability of pesticides to protect their crops against insects, weeds and diseases compared to many other agricultural markets of the world. The disincentive to investment of minor crop pesticide registrations in other countries is further exacerbated by Australia's small market size. It is important to note that access to crucial, innovative crop protection products fosters economic growth and rural development. Many minor crops are cultivated by small-scale farmers and specialty growers who rely heavily on the availability of effective pest control options. By enabling the registration of suitable pesticides for these crops, the process bolsters the productivity and profitability of these farmers, contributing to the stability and vitality of local economies. Moreover, it incentivises innovation and research in the agricultural sector, leading to the development of novel and sustainable pest management solutions that benefit both minor crop producers and the broader agricultural community. Through enhanced and improved availability, the products and innovations of the plant science industry will continue to foster and enable Australia's goal of producing $100 billion in farm gate output by 2030, as well as supporting environmental conservation and the protection of Australia's rich natural biodiversity.

CropLife Australia

August 2021

Improving access to agricultural and veterinary chemicals

Exposure Draft - Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2021



INTRODUCTION

CropLife Australia is the national peak industry organisation representing the agricultural chemical and plant biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of crop protection and agricultural biotechnology products. CropLife's membership is made up of both patent holding and generic Australian and international companies and accordingly, CropLife advocates for policy positions that deliver whole of industry benefit. The plant science industry provides products to protect crops against pests, weeds and diseases, key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $20 billion annually to the Australian economy and directly employs thousands of people across the country.[1]

CropLife is pleased to provide input to the *Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2021* (the Order). It is essential to ensure the incentives offered actually deliver on the stated goal of delivering new or minor use registrations to Australia's farmers, ensuring they are not disadvantaged compared to those in our major ag trading nation competitors. While many of the provisions in the Exposure Draft certainly have the potential to accomplish the addition of new uses, there will need to be substantial evaluation of the incentives and limitations placed on them to prevent "gaming" or manipulation of the data protection periods to delay the addition of uses or prevent competitors from entering the market. As currently stated, these potential circumstances both exist.

Additionally, as phrased, a large portion of products in the system would already qualify for many of the crop/pest combinations enabling extended data protection, suggesting there may be data protection period extended without adding a significant amount of new uses.

The plant science industry

The plant science industry's crop protection products include fungicides, herbicides and insecticides critical to maintaining and improving Australia's agricultural productivity to meet future global food security challenges. Each of these products is rigorously assessed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) to ensure they present no unacceptable risk to users, consumers, the environment and the trade of agricultural produce.

In 1995, it took the assessment of an average of 52,500 compounds to develop one effective crop protection chemical active constituent. It now requires the assessment of more than 140,000 compounds and expenditure of more than $400 million over an 11-year period to bring just one successful crop protection product to the market. More than one-third of this cost directly relates to compliance with regulation and registration requirements. Without access to these tools, farmers could lose as much as 50 per cent of their annual production to pests, weeds and diseases.

[1] https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf

A Deloitte Access Economics report released in 2018, 'Economic activity attributable to crop protection products', estimates that up to $20.6 billion of Australian agricultural output (or 73 per cent of the total value of crop production) is attributable to the use of crop protection products.[2]

Crop protection products are crucial to modern integrated pest management techniques and systems used by farmers. Access to fewer crop protection tools would facilitate faster development of resistance among targeted pests, diminishing the efficacy of remaining chemical options. The economic impact of weeds alone is estimated to be over $4.8 billion each year, or $13 million per day.[3]

The current regulatory system for agricultural chemicals in Australia is scientifically competent, technically proficient and globally recognised. CropLife's only significant concerns with the current system relate to inefficiencies and unnecessary overlaps. The regulation of crop protection products in Australia must be efficient and effective so that Australian farmers have access to the innovative tools the plant science industry provides. This will improve the ability of Australian farmers to be sustainable, productive and internationally competitive.

[2] *https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf*

[3] *https://invasives.com.au/wp-content/uploads/2019/01/Cost-of-weeds-report.pdf*

ITEM 2: INCENTIVISING THE REGISTRATION OF CERTAIN USES

2.1 Extensions to protection and limitation periods

Extensions to particular protection periods (data protection) and limitation periods to incentivise the registration of certain uses is a concept wholeheartedly endorsed by CropLife and has been a policy and advocacy position for many years. As such, CropLife supports the incentives stated, such as introducing particular kinds of prescribed uses of chemicals, to gain extensions to protection periods and limitation periods similar to approaches applied internationally. While we support provisions extending data protections, the described mechanisms must be thoroughly evaluated to ensure they do encourage more uses to be included in the product registration and on the label, through the initial registration or a variation to the registration.

As stated, while we are supportive of the initiative in general, we have substantial concerns with the delivery of the protection periods.

Regarding the provision that applications be made at least three years before the protection period or limitation period ends (if applicable) (new subsections 34KA(3) and 34MA(3) of the Agvet Code, to be inserted by the Bill), a notification or flag on PUBCRIS will need to be introduced to clearly indicate that an eligible application has been made. The APVMA currently has the requirement to publish summaries of applications made, but we are aware of instances where applications haven't been clearly published and the current system is not searchable. As such, we feel it cannot be relied upon in its current form.

2.2 Proposed approach

Relating to the proposal that the extensions would operate by providing that information with an existing protection period, or new or existing limitation periods that relate to items 1, 2, 3, or 4 of the table at subsection 34M(1) of the Agvet Code, which may be extended for up to five years if certain requirements are met, we suggest that items 5 and 6 also need to be captured. As written, a situation could arise where an applicant submits in year 6 with a variation application and gets registration in year 7 for uses that would add five years limitation, but because this is indicated to only apply to the first 4 items, the original underlying dataset would have its limitation period extended to 15 years in total. You would, however, only get five years on the new data submitted with the variation application (so it expires 12 years after the original registration), which will become confusing to administer.

Item 3 of Table One indicates a novel means of extending limitation periods to generic or otherwise orphaned products. In concept we support this, however, the means by which this is accomplished requires a registrant to take an existing product with all data protection expired but copy the formulation onto a new registration number with a slightly different name, along with new use patterns and secure up to 10 years use limitations. If this is the intent, we suggest it would be more transparent to just include variation applications from the start.

The proposal that an application under section 26B of the Agvet Code (prescribed variations) would be an additional eligible application for extending an existing protection or limitation period is somewhat perplexing, as this is required to be made if certain details on the Register are found to be incorrect. The industry is unaware of any such event that could ever trigger an extension to data protection. Without a defined reason to include this, it just creates additional complication and requires the APVMA to develop systems and processes to cater to something that will never be used. The well documented failure of the 'interchangeable determination' regulations is a classic example of the impact ill-conceived regulations can have. These mistakes cannot continue to occur as they waste resources and distract the APVMA from higher priority reforms.

Where the information provided in connection with a variation application is deemed to be less valuable than the original information, there are no proposed extensions for this information. It is puzzling that the underlying data from the original submission is proposed to be limited for a longer period than the new data submitted for a variation. Variation applications are never stand alone. They rely on the originally submitted data. It only makes sense that they stay aligned with expiration dates for limitation periods. To do otherwise will make it seem like the limitation period on the later added use has expired (i.e., if the extension is to add wheat, no study titles in the data protection list will actually say wheat so it could be incorrectly assumed that the limitation period for wheat has expired).

Where the government proposes to restrict the extensions to information given in connection with agricultural chemical products in the first instance, the proposed order will establish the framework for expanding this to active constituents and veterinary chemical products in the future. Clarity is requested to discern whether "first instance" qualifies only the first applicant who submits. At worst, this risks encouraging incomplete, poor-quality submissions to be made that waste the APVMA's time and which will not deliver on the promise of better access to industry.

The worked examples of how extensions are to be applied do raise further concerns about the complexity of the process. The examples given illustrate some of the needless complexity. As written and demonstrated, a product could end up with limitation periods expiring for the data associated with the variation applications at two different times. This will be essentially meaningless, as the uses wouldn't be available to a third-party until the original data's extended period of protection expires.

2.3 Proposed extension periods

Clarity around the uses on crop groups (as established by the APVMA) is also requested. Frequently, there are situations where there is a legitimate reason the whole group can't be included. For example, several herbicides are safe for cereals other than oats. In these cases, it is currently unclear if the product will still qualify for the extension, or if it will be ineligible because the whole group is not represented. Specific triggers for exemptions would be welcomed, without submitting a "crop group" that limits to one crop on the group, exempting all others.

The limitation periods proposed on priority uses determined through the collaborative forum established under the Improved Access to Agricultural and Veterinary Chemicals Initiative are also confusing and poorly presented. At minimum, the list should have the scientific names for all pests listed to avoid confusion and prevent gaming the system. For example, Tea tree has a general 'psyllid' listing but there are many 'psyllids'. You could be eligible for extended data protection by registering a psyllid that is a pest in a different crop that isn't actually of concern for tea tree. In this case, the benefit to growers is not realised, but by the procedure listed, would still qualify for a limitation period extension.

Further, as the crops/pests' tables are currently listed, there are several pests listed by their common name, each associated with an extended limitation period on the same crop. They all, however, have the same scientific name. By this current table, it would be possible to obtain 18 months extension of limitation period on the same species. Lastly, a clear definition of "suppression" vs "control" would be a valuable addition to these priority uses. It is neither currently clear which claim would trigger the extended limitation period, nor what those terms specifically delineate.

The proposal also lacks a policy position on the implication of adding one or more crop groups, as well as a priority use relevant for those crop groups. For example:

- Adding Pome Fruits and Stone Fruits would allow a 12-month extension (6 months for each)
- Adding Alternaria (from a Pome Fruit listing) and Botrytis (from a Cherry listing) would allow a 12-month extension (6 months for each)
- But what if Pome Fruit and Stone Fruit were added as crops with uses for Alternaria and Botrytis, would the extension be 24 months?

CropLife supports the reflection of the proposed crop group related periods in the difference in effort required by applicants to generate data to support a particular crop group as per the 'extrapolation and data waiver guidance within crop groups' table that is set out in the APVMA's document *Representative crops and extrapolation principles for risk assessment and data waivers*. The regular review of the Order to include relevant new priority uses established through the collaborative forum and to remove priorities that have been addressed, is likewise supported. The suggested 12-month phase-out period, however, would likely be too short of a timeframe to allow for the potential need to do two seasons of trials to establish efficacy. In light of this, it could take two to three years before an application could be properly prepared. Such a short phase out will disincentivise investment in new uses.

Similarly, some of the provisions for the limitation periods on particularly small market crops may not capture the extra effort in generating data. This has been recognised in the 18 months extension for some spices and edible fungi. As currently laid out, considerable effort could be employed in navigating a "course of least effort" to establish the maximum data protection or limitation on use period, without noticeably addressing the shortfalls in product availability for specific crop and pest examples. The aim is to incentivise new uses and increase access to chemicals.

Further to this, we suggest more provision to prevent the gaming/manipulating of new use applications to product registrations may be needed. At worst, new uses could be delayed from registration, as registrants calculate their maximum limitation periods. This ability to game the proposed system runs counter to the stated *intent* of the Order, which is to incentivise new uses. Further incentives on a "point scoring" system could be included to incentivise the earlier introduction of new and minor uses, such as a multiplier effect for the addition of uses earlier in the 10-year limitations on use period.

2.4 Ending an extended period or limitation period

CropLife also supports the proposal that the Order allow for ending the protection or limitation period extension (such as where the use that led to the extension is removed). This will be a good preventative measure to ensure the protection and limitation periods are not manipulated unfairly, either through the lodging of junk applications or poor data, which prevent the entry of other registrants, or as stipulated in the example, the removal of prescribed crops or pests from the label once protection or limitation periods have been extended.

Indeed, this is but one of the examples by which the system could be "gamed" by registrants more interested in obtaining the protection and limitation periods than extending new uses to Australian farmers. CropLife agrees it would be prudent to ensure the APVMA has a mechanism to deal with this or other circumstances where it would be appropriate to end the extension period.

2.5 Application summary

CropLife supports the concept of "springboarding" whereby competing chemical companies use knowledge of the expiry date of a protection period or a limitation period to determine when they may be able to submit an application, referencing that information, to progress the development of their own generic products or innovative re-formulations and new use patterns. As noted previously in this submission, however, this system is not currently working reliably enough to inspire confidence. The only way this is fair and equitable is if a flag is raised on PUBCRIS that an eligible application has been made.

Hence, the proposal to amend regulations to provide for the summary of the variation application to include an indication that the existing protection period or limitation period may be extended as a result of granting the application is supported but must be bolstered.

ITEM 5: DETAILS THAT DIFFER FROM THE REGISTERED PARTICULARS

Standards for minor differences in constituents, concentration, composition and purity

CropLife agrees that during manufacturing processes there can be reasonable variations in the constituents contained in a chemical product (such as trace amounts of another constituent in the end product) as a result of both the concentration of constituents in a chemical product and the composition or purity of constituents in a chemical product.

CropLife maintains these minor differences may be entirely reasonable, particularly where they do not affect the safety or efficacy of the registered chemical product. The Crop Protection and Stewardship Committee of CropLife has, for considerable time, been actively engaged with the APVMA on this subject. Given that proposed regulation 41 does not allow for fundamental changes in a product's constituents, concentration, composition or purity, CropLife will work with the APVMA to develop the standards for minor formulation variations, so they come into effect shortly after the regulations are enacted.

ITEM 6: EXCLUSION OF AGVET CHEMICALS FROM REGULATION

CropLife supports enhanced means such as this to refine the APMVA product category regulatory scope. Indeed, reducing the APVMA's product category regulatory scope is necessary to improve efficiency quickly and dramatically in the core registration operations of the APVMA. Dairy sanitisers, anti-fouling paint, swimming pool chemicals and cleaners should not be regulated by the APVMA. If necessary, these product types can be more appropriately regulated by another agency. Removing these products from the APVMA's regulatory scheme will allow it to focus its resources on its core business of assessing, approving and registering agricultural and veterinary active constituents and products.

Removing the regulatory duplication of whole viable seeds is also required. Whole viable seeds that are genetically modified with incorporated pest and/or disease control, are currently regulated by the Office of the Gene Technology Regulator, Food Standards Australia New Zealand, the Therapeutic Goods Administration and the APVMA. Exclusion of whole viable seeds from regulation as an agvet chemical is a necessary and viable solution with significant efficiency gains, without compromising human health or environmental safety.

To accomplish this, it is recommended that Schedule 3, Part 3 of the Agvet Code be additionally amended to create a subsection that excludes whole viable seed and propagation materials for grafting or planting and declares them to be non-agricultural chemical products.

A technology is being developed overseas that improves the efficiency of the well understood process of applying an electrical current to a plant in order to destroy the plant[4]. This efficiency gain is via the application of conductive liquid at the front of the applicator that lowers the energy required when the electrical current is applied at the rear of the applicator. This technology has application in fallows, pasture renovation, interrow weed control, preventing seed set of resistant weeds prior to harvest and crop desiccation. There may also be some benefit in the control of other pests such as ergot in ryegrass or insects that congregate at the top of a plant where the electrical current is applied.

Whilst the electrical current per se would be excluded from the definition of an agricultural chemical product (as it wouldn't be defined as a substance), the conduction fluid appears likely to require registration in Australia and not Europe due to the 'indirect' wording in the definition. Rather than disincentivise Australian growers getting access to this technology, an exemption should be established now. Suggested wording for the exemption is "Any conductive substance used in conjunction with electrical current as a method of destroying any plant or destroying, stupefying, repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest".

[4] *https://crop.zone/*

Similarly, in Australia the CSIRO is developing a sprayable biodegradable polymer as an alternative to non-biodegradable plastic sheeting[5]. Whilst the primary function of this technology is to prevent water loss, it also provides weed (and possibly other pest) suppression so could be captured by the definition of an agricultural chemical product. An exemption does exist for a 'physical barrier to a pest' but this excludes substances 'released into the environment' so would not apply to this technology. Suggested wording for the exemptions is "Any substance which is a biodegradable polymer applied to the soil that presents a physical barrier to a pest or plant".

Several other innovative technologies are expected to have similar potential to be captured by the current definition of an agricultural chemical product, so it is suggested a specific request be made during the next round of consultation to receive suggestions for further exclusions that can be considered by the Department.

[5] *https://www.csiro.au/en/research/production/materials/sprayable-biodegradable-polymer-membrane*

CONCLUSION

CropLife and our members are supportive of provisions to extend data protection and limitations on use in exchange for the addition of new or minor uses to product labels. In the current structure, however, there are substantial concerns that the potential exists for companies to "game" or manipulate the system.

The structure for additional data protection measures is complex, convoluted and difficult to navigate. In many cases it is difficult to understand how the pest species/crop combinations were reached.

Owing to both this complexity and lack of clarity surrounding the incorporation of many of these data protection and limitation extension periods, CropLife recommends more in-depth consultation with both the APVMA and the Industry. This would serve to better facilitate a streamlined process by which new uses and innovative formulations may be rewarded with extended data protection provisions, as well as allow for these processes to be introduced at the APVMA without adding needlessly complex and burdensome administration. As previously indicated, CropLife's significant concerns with the current system relate to inefficiencies and unnecessary overlaps. We do not wish for these measures to add to this inefficiency.

Perhaps most importantly, however, is that this process must now be expedited. As these provisions are public and the broader industry is aware of the forthcoming changes, they must be reviewed and implemented with all possible haste. For many reasons, we do not wish registrants to begin strategically withholding applications. Firstly, this will result in the opposite of the intended outcome, meaning delayed applications for new uses, while registrants calculate means of obtaining the maximum possible data protection and limitation periods. Secondly, a delay here, while registrants watch the process unfold, would mean that once the amendments are implemented the APVMA could be comprehensively overwhelmed with applications.

CropLife and our members have constructively engaged for years in all previous reform agendas and proposed specific initiatives to improve the regulatory system, both in its effectiveness and its efficiency. Despite our frustration with the slow process and lack of proper implementation of these reforms, we remain committed to continuing to work constructively with the Federal Government to ensure Australia has the world's best agricultural chemical regulator.

To whom it may concern,

Response to the Australian Pesticides and Veterinary Medicines Authority (APVMA) update of its guidelines for determining a minor use permit from the Custard Apples Australia Management Committee.

The Custard Apples Australia Management Committee considers that:

- The current guidelines for determining a minor use permit have worked for the custard apple industry.
- The reapplication system for use of minor use permits as administered by Hort has worked for the custard apple industry.
- The custard apple industry remains a 'minor crop' industry as outlined in Schedule 1.
- The custard apple industry requests inclusion in the second round of consultation following the draft release of the new guidelines.

Your sincerely,

John Graham
Secretary, Custard Apples Australia
0416 219 105
Custard Apples Australia Inc.

12 June 2023

Director, Permits and Minor Use
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Email: enquires@apvma.gov.au

Response to APVMA call for public comment on the review of the guidelines for determining a minor use

Thank you for the opportunity for the Grains Research & Development Corporation (GRDC) to provide a response to the call for public comment on the APVMA's review of the guidelines for determining a minor use.

The review is seen as an important initiative in the functioning of the minor use scheme and viewed as critical in the delivery of much needed access to crop protection products for Australian agriculture. From that perspective GRDC would like to provide the following remarks. These comments are provided to assist in the updating of the minor use scheme, focusing on the need for more transparent criteria, consideration of economic return, and engagement with industry stakeholders.

To more fully and meaningfully engage in the consultation process it would be helpful if the APVMA could provide background information on how the current criteria for determining minor use were chosen and applied. For example, what cut-offs were used for production values or export quantities in determining a crops status? Having this information available would enable more detailed input to the consultation.

Also, it is unclear from the consultation document whether the APVMA intends to update both the 2002 Guideline for determining minor use[1] and the 6A Permits Guideline[2]? Clarifying whether both guidelines are included in the proposed update would be helpful. As the 6A Permits Guideline provides information on what may be considered minor[3] in terms of economic return and reasonable grounds for issuing permits[4].

In terms of specifics, the current Schedule 1 and 2 criteria of the 2002 Guideline appears to be driven more to address regulatory risk than the question of potential economic return.

While the APVMA must be satisfied the proposed use would meet safety, trade and efficacy criteria[5], i.e., regulatory risk is important, it is believed that greater emphasis should be placed on assessing the economic return of a minor use. As acknowledged in the Guideline, determining sufficient economic return

[1] https://apvma.gov.au/node/10931
[2] https://apvma.gov.au/node/984
[3] Permits 4(1)(c) https://apvma.gov.au/node/984
[4] Permits 4(5)(d) https://apvma.gov.au/node/984
[5] AgVet Code Regulations Section 112 (2) (c) and (d))

can be '*somewhat difficult*', however it is suggested that greater consideration be given to developing ways to characterise the scale and nature of needs, as either minor or major, rather than considering uses from the perspective of a crop's classification.

It is believed that Schedule 1 criteria such as dietary consumption, value of production and export quantities relate to regulatory risk and therefore have little applicability to economic return in the context of determining minor use. The Schedule 2 limits of 10% of national area or 10,000 ha provide cut-offs for a minor use in a major crop, but their basis is unclear and are more likely relevant to assessing regulatory risk. GRDC supports the view, stated in the 2009 OECD minor use paper[6], that "*it is important to ensure that determinations of what are minor uses (derived via the economic return approach) remain independent from determinations of regulatory risk assessment*". Without that distinction there is a risk that the minor use scheme could be too inflexible.

The development of criteria, relating to needs, would provide a minor use framework that would be more responsive to industry need and align better with the legislated definition. For example, uses nominated by industry groups, that have failed to garner any registrant interest, could form the initial basis for consideration.

Section 4(5)(d)[4] of the 6A Guideline, already address some aspects of need in terms of what are reasonable grounds. However, what are needed are additional measures to determine the scale and nature of the need, i.e. the reasonable grounds in an economic context. Aspects such as generic vs proprietary compounds and the effects any data protection provisions or incentives could be considered. It is suggested that this is an area where further expansion, coupled with amending the criteria underpinning Schedules 1 and 2, would be of benefit.

The APVMA is also encouraged to consider including such factors as the availability of management options, problem distribution and frequency to better help inform the question of potential economic return, or lack thereof, and whether a use could be considered minor. Having access to such information would be of greater value in assessing a use in terms of economic return and determining its minor or major status rather than from categorising crops.

It is therefore proposed that the APVMA engage further with agricultural industries to reassess the current criteria. A starting point could involve the extension of the principle behind the emergency use definition, i.e., a "*genuine belief that the use is required*"[7] to include minor use.

From the perspective of identifying and prioritising industry needs, DAFF currently operate a ranking process of nominated crop protection needs in the awarding of Commonwealth grant funding. While not applicable to the determination of minor use it is suggested that an analogous approach could be used in building needs profiles and crop priorities with respect to assessing minor use.

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[6] ENV/JM/MONO(2009)39

[7] AgVet Code Regulation Division 1.1 Definitions Regulation 3

Regards

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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.

13 June 2023

Director, Permits and Minor Use
Australian Pesticides and Veterinary Medicines Authority
102 Taylor St
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Re. UPDATE TO GUIDELINES FOR DETERMINING A MINOR USE

Horticulture Innovation Australia Limited (Hort Innovation) is the not-for-profit, grower-owned research and development corporation (RDC) for Australia's $15.1 billion[1] horticulture industry. In this capacity Hort Innovation works towards meeting both the current and strategic needs of horticultural industries across several areas, including chemical access.

Horticulture is one of the most diverse sectors in agriculture with a wide range of crops and crop types grown to meet the needs of the Australian community. Ensuring growers can access the tools required to enable them to be both productive and profitable is a significant need Hort Innovation addresses across the diversity of horticulture industries. Agvet chemicals are one such tool, where at times grower access can be problematic. This issue can be particularly acute for growers of minor crops as a result Hort Innovation is supportive of initiatives that aim to update the Guideline in determining minor use.

Hort Innovation offers the following observations and comments on the consultation paper to assist in developing the guideline further.

Hort Innovation has concerns regarding the current criteria on which the existing minor use guideline is based. These criteria seem to address two separate issues: the potential "importance" of a crop and the necessary risk assessments for undertaking the proposed use. However, neither of these adequately addresses the determination of whether a proposed use is minor.

The guideline states that the classification of major/minor in Schedule 1 is based on five elements: dietary consumption, value of production, export quantities, area under cultivation, and production volumes. However, it remains unclear why these elements were chosen and how they were applied to classify crops as major or minor. The following are questions pertaining to the use of these elements:

1. Dietary consumption: It is unclear how dietary consumption, an important factor in risk assessment, has been utilized to determine whether a crop is classified as major or minor. Has a specific threshold value been applied to mean daily consumption data to determine the prominence of a commodity in the Australian diet? If so, how was that threshold determined, and how were the different components of consumption taken into account? For instance, orange juice represents a significant proportion of

[1] Hort Innovation (2020). Australian Horticulture Statistics Handbook 2019/20.

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orange consumption in the Australian diet, accounting for over 80%. In 2021-22, Australian orange juice production was 16,500 MT, while imports were estimated at 18,000 MT, which makes up over 50% of consumption[2]. Therefore, it may not be appropriate to use dietary consumption levels or thresholds alone to determine whether a proposed use should be considered major or minor. Another example is sweetcorn, where a significant portion of the national production is imported (20,684 tonnes, equivalent to one-third of the total[3]). If dietary consumption patterns are to be used in determining minor use, the rationale for inclusion needs clarification, and the consumption data used should be refined to account for imports.

2. Value of crop or animal: It is unclear why the value of a crop has been considered when determining whether a proposed use can be classified as minor. For instance, mushrooms, despite being a relatively high-value crop valued at $437.7 million in 2019[4], are classified as major. However, the mushroom industry is small, with around 70 growers nationally, low dietary consumption (< 0.1 g/kg bw/day[5]), and an annual production volume of less than 50 tonnes[6]. Additionally, due to the unique nature of the crop, the availability of suitable crop protection products is extremely limited.

   Conversely, if we compare the relatively nascent specialty crop like truffles, which had a production value of $50 million[7] in 2020 (estimated based on a value of $2500 per kilogram and over 20 tonnes of production), it becomes apparent that using crop value alone does not adequately assess whether a proposed use in a crop is minor. Considering major vegetable crops such as cabbages ($41.6 million) or cauliflower ($47.4 million) have lower production values[8].

3. Export quantities: Fresh export volumes across horticulture vary significantly, ranging from over 180,000 tonnes of oranges to 565 tonnes of head lettuce or 561 tonnes of apricots in 2019[9]. It is challenging to understand how such information was applied and whether it provided any meaningful insights into determining whether a proposed use in a crop is minor. Concerns over export compliance would be better addressed through the APVMA's Trade Advice Notice consultative process, rather than relying on export volumes as a criterion.

4. Area under cultivation and production volumes: While these elements provide a relatively straightforward way to classify a crop's relative importance or potential for economic return, they do little to determine whether a proposed use is minor. On that point Hort Innovation finds the Case study 2 comparison somewhat puzzling as sweet corn sits within crop Group 20–Cereals grains, not Group 12–Fruiting vegetables, other than Cucurbits. That aspect aside, Schedule 2 does provide a means of addressing the question of minor uses in a major crop; however, it is unclear how the thresholds of 10% of national acreage or 10,000 hectares were determined. Were these thresholds derived to minimise any impacts on dietary consumption, production or export volumes? If so, Hort Innovation has concerns given the potential uncertainty regarding the origin of consumed commodities for a number of commodities.

[2] USDA FAS Report AS2022-0030
[3] VG12083 Understanding the nature, origins, volume and value of vegetable imports. Hort Innovation Report
[4] Australian Horticulture Statistics Handbook- Vegetables 2019
[5] 2017 MRL Food Consumption
[6] Agricultural commodities, Australia and state/territory and ASGS regions - 2020-21
[7] https://ausbizmedia.com/australian-truffle-industry/
[8] Australian Horticulture Statistics Handbook- Vegetables 2019
[9] Australian Horticulture Statistics Handbook- Vegetables 2019

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horticulture.com.au

Hort Innovation suggests that in view of these concerns the APVMA should concentrate on developing and implementing a pest-based approach to the determination of minor use; rather than relying on criteria such as crop statistics or dietary consumption. Numerous horticultural industries have produced profiles (known as SARPs) that outline and rank importance of pest management needs. It is believed that consulting such profiles, or similar, would be beneficial in the APVMA's assessment process. Using a pest-based approach, would also ensure that niche pest problems on major crops are adequately covered.

It is therefore proposed that the APVMA consider emulating the approaches followed internationally and consult with industry groups in the creation of a matrix to prioritize pest management problems based on their characteristics and availability of management solutions. The development of such a resource would help guide the APVMA's assessment and engagement with state coordinators and stakeholders in the consideration of minor uses going forward.

Yours sincerely,

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Maize Association of Australia

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7 June 2023

Director, Permits and Minor Use
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001
enquiries@apvma.gov.au

RE: Review of Guidelines for Determining Minor Use

The Maize Association of Australia (MAA) is the peak association that represents and encompasses all sectors of the maize industry in Australia. It serves as the primary industry organization for maize-related matters in the country. As the peak association, the MAA's primary objective is to promote and support the development, growth, and sustainability of the maize industry in Australia. It works towards achieving this goal by addressing issues and challenges faced by the industry.

MAA therefore appreciates the opportunity to contribute to the APVMA's updating of its Guideline for determining minor use.

As MAA has flagged previously it is believed that the categorization of maize as a major crop is flawed when viewed against the factors upon which the determination was made, i.e., "*volume of commodity production, area under cultivation, dietary consumption, value of the crop and export quantities*".

To provide some context MAA would like to highlight that maize grain can be grown for a number of different purposes, i.e., for human consumption, industrial purposes and stockfeed. The maize plant itself can also be grown for silage. The differing uses of maize grain, due to potential specialty needs tend to preclude interest from registrants.

The volume of maize grain production in 2021/22 was estimated to be 430 kt, extremely small when compare to wheat at 36,237 and barley at 14,377 kt, respectively. The same situation exists when area planted is considered. It is estimated that the total Australian maize crop (used for grain or silage), including popcorn, is between 150,000 and 180,000 ha per season (MAA data), as compared to barley at 5.1 million hectares, wheat at 12.7 million hectares or oats at 842,000 ha[1].

From a dietary exposure perspective, consumption from all sources was estimated at 0.16 g/kg bw/day[2], comparable to the consumption of poultry edible offal. A level unlikely to be considered major when viewed against the level of wheat consumption of 1.967 g/kg bw/day[3].

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In terms of value, the national crop was estimated at $150 mio in 2020, while the crop value of barley was estimated at $2,489 mio. For exports the situation is repeated with maize exports not significant with less than 31.5 kt exported, i.e., ~21% of national production in 2022/21[4].

While it is acknowledged that maize is listed as the representative crop for crop Subgroup 20E, Maize cereals, MAA does not believe that this is sufficient to justify the crop being considered major, particularly given the subgroup only consists of three commodities.

Therefore, given the information outlined above, MAA proposes that the APVMA amends the categorisation of maize to be minor crop.

Regards,

Elizabeth (Liz) Mann
Executive Officer
Maize Association of Australia

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Review of guidelines for determining a minor use

Submission from Minor Use Foundation Inc.
5 June 2023

The Minor Use Foundation Inc. is pleased to make the following submission to the APVMAs review of guidelines for determining a minor use. Our submission is specifically in relation to minor uses in crop protection. The MUF would be pleased to further elaborate on any parts or provide additional information in support of this submission and meet with the APVMA if required.

The MUF recommends that for accessing approvals via permits in Australia the focus of a guideline for determining minor uses be uses that lack any or have insufficient crop protection solutions.

Our submission provides reasons explaining this recommendation as follows.

About the Minor Use Foundation

The Minor Use Foundation Inc. (MUF) was established in 2018. The MUF works with growers globally to identify needs and conduct scientific research to facilitate access and minimise trade barriers to the safe and effective use of crop protection tools for minor crop growers around the world. In particular the MUF:

- identifies global priority pests and diseases affecting minor use cultivation.
- facilitates data-sharing initiatives to maximize the utility of investments and R&D in minor uses and specialty crops.
- supports the establishment of high-quality minor use programs and minor use research facilities globally.
- conducts scientific research globally for the establishment of pesticide registrations in individual countries and international trading standards.

General comments on what are minor uses

The diversity of agriculture is immense, where globally and within each country agriculture comprises hundreds of crops. The Codex Classification alone which we note the APVMAs own crop grouping list adheres to recognises more than 900 different agricultural commodities. While many of these crops are not likely to be commercially produced in Australia, it is very likely that at least several hundred are. On this basis, it is reasonable to estimate, and it must be acknowledged that **globally and within Australia >80-90% of uses, by number (not product use or sales volume), are likely to be minor uses**. They are also a significant component of the agricultural diversity and its importance to a country's economy, culture and for contributing to a healthy diet for its citizens. To support these comments and for additional context:

- A report from the EU Commission to the EU Parliament in 2014 stated: "*Minor uses are mostly connected to minor crops that together are valued at about €70 billion per year, which is 22% of the total EU plant production value*" and "*The term "minor use" may give the impression that their economic dimension is also minor, but is the contrary. Minor uses concern in reality high-value speciality crops, such as fruits and vegetables, ornamentals, nursery crops (plants for planting), and aromatic plants*" (refer: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0082).

- A report of the US International Trade Commission in 2021 stated: "*specialty crops typically constitute nearly one-third of the annual value of U.S. crop exports" (refer:* . https://www.usitc.gov/publications/332/pub5160.pdf).

While the MUF notes that current Australian legislative definition of a minor use is not for review the MUF would like to state that it broadly agrees with the definition which briefly states "… *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 …*". Although from a somewhat different and more practical perspective **the MUF experience is that agricultural producers tend to identify minor uses as being critically important pests and diseases affecting their production systems that suffer from either no or insufficient solutions to meet market/consumer requirements**. The MUF contends that while framed differently the Australian legislative definition and what we hear defined by producers as minor uses are one and the same.

It is widely recognised that all crops suffer from minor uses albeit to differing levels. They affect both crops on grown on a small scale and those grown on a larger scale, often referred to as minor/specialty crops or major crops respectively. While the current APVMA guideline attempts to recognise this through the provision of three schedules by (i) classifying major crops, (ii) % thresholds and (iii) economic modelling as the discussion paper notes these can result in anomalies. The resultant outcome is that not all minor uses are appropriately recognised creating difficulties for both permit applicants and the regulator.

The classification of crops as minor or major based on factors such as area of production or % thresholds as noted above only results in anomalies. The APVMAs discussion paper for this consultation outlined several factors seeking feedback on their applicability and usefulness in classifying major and minor uses. The MUF has examined each and considers that most factors are important for determining data requirements for risk assessment purposes BUT that they do not serve as an absolute surrogate for defining a minor (or major) use. We articulate further on each of those suggested factors in Attachment 1.

The level of commercial interest in pursuing registration of a use differs greatly between active ingredients that are new and covered by patent or data protection as opposed to when those compounds become generic. Economic modelling is complex and will differ from product to product and between uses for many different commercial reasons, some of which are likely to be Commercial Business Information to the product registrant. This information is not readily or likely to be made available for producers/permit applicants to develop sound business cases justifying their uses as minor, or the regulator for appropriately assessing those.

At the MUF the focus of our activities is on assisting producers accessing solutions to crop protection needs that are not pursued by the commercial sector. **We do not differentiate between crops as minor or major or perform economic return analysis but rather pursue unmet crop protection needs that the producers identify as priorities**. The MUF takes this approach based on our personnel's many decades of experience working with affected producers. The MUF understands that the commercial sectors business model is premised on new ingredient discovery and registration of its product portfolio into crops and uses which will provide sufficient economic return. Uses that do not meet the business threshold simply do not gain commercial interest and are not registered, therefore resulting in minor uses.

The MUF recommends that for accessing approvals via permits the focus of a guideline for determining minor uses needs to reflect what 'uses' are minor uses as described by producers as

opposed to seeking to classify crops as minor or major, or examining % thresholds and/or requiring economic modelling.

Scope and application of the definition within Australia

The MUF notes that **the legislative definition of a minor use and the associated guideline only applies to APVMAs functions for the issuing of permits** and does not appear to have relevance to any other regulatory functions of the APVMA such as product registration, including data protection provisions. At this time and given this limited application we believe that any new guidance must be made with respect to the issuing of permits for minor uses and our submission reflects this. Should future opportunities arise where minor uses are formally recognised in the legislation for registration purposes the MUF would be pleased to comment on what guidance and related regulatory incentives could be considered to facilitate the registration of minor uses to lessen the requirement for permits.

In addition to the guideline referred to as part of this review (https://apvma.gov.au/node/10931) the MUF notes that the APVMA has published a 6A Guideline on Permits (https://apvma.gov.au/node/984) and considers it is also highly relevant to this review, in particular in determining if a permit should be issued. The relationship between these two documents is not clear and requires examination. Although it is understood that the APVMA must have regard to its published 6A guideline when considering permit applications.

The 6A guideline includes sections on "*What is a minor use*" and "*What are reasonable grounds*" and the MUF believes that these sections provide further guidance as to the intent of permits as it relates to minor uses. The 6A guideline with or without modification could suffice replacing the guideline that is the subject of this review. For example, despite a use qualifying as a minor use via Schedule 1, 2 or 3 of the current guideline, the APVMA must also determine that 'reasonable grounds' exist for the issuing of the permit (section 112 of the AgVet Code).

The section on '*What are reasonable grounds*' in the 6A guideline includes that the use is:

- *a minor use, emergency use or for the purposes of research,*
  AND
- *other considerations if it is a minor use (or emergency use) including the presence of existing registered products for that use.*

Therefore, a key consideration for the issuance of a permit is the determination that reasonable grounds exist. The 6A Guideline states '*there will not be reasonable grounds if there are suitable and effective registered chemical products or approved active constituents with the same purpose*'. This implies irrespective of the use being a minor use (or emergency use) that permits are only deemed appropriate for uses that are not sufficiently addressed by existing registered options. We believe the consideration of existing registered options has been implemented to recognise that registration is the primary mechanism of approval and that where registered uses exist, they are supported, and that permits are only a secondary mechanism. The MUF supports this approach. To do otherwise would only undermine or adversely affect the commercial interest of registrants in registering uses, possibly further exacerbating the presence of minor uses and increasing a reliance on permits.

Therefore, a guideline that seeks to identify 'crops and situations' as minor would appear to have no bearing on the decision to issue a permit, as the *use* must still satisfy the test of reasonable grounds. Further the legislative definition of a minor use refers to *uses*, not crops or situations, so classifying

them would appear to add little benefit when the key test is if reasonable grounds have been met for issuing a permit for a given *use*.

Finally, we also note that the 6A guideline under the section titled "What is a minor use" states:

- *Ordinarily, we will not issue a 'minor use' permit in relation to an approved active constituent or a registered chemical product, to permit use not covered by the approval or registration, to:*
  1. *the holder of the approval or registration, or*
  2. *a person principally responsible for the development, manufacture, marketing, distribution or commercialisation of the active constituent or chemical product the subject of the approval or registration*
- *In these circumstances, and where the holder or other relevant person obtains a commercial benefit from the supply of the approved active constituent or registered chemical product, the holder or person should apply for a new registration or approval, or to vary the relevant particulars or conditions of the registered chemical product or approved active constituent, as the case may be.*

The above implies that the APVMA considers that applications for minor use permits should principally come from users / producers.

Conclusions & Recommendations

The MUF believes that the current 6A guideline would suffice replacing the guideline that is the subject of this review. Our liberal interpretation of the 6A guideline and as discussed above is that permits for minor uses are principally to deal with circumstances that are:

- for uses that lack any or are not sufficiently addressed by existing registered options, and
- applied for by an affected producer or producer group.

The MUF recommends that for accessing approvals via permits in Australia the focus of a guideline for determining minor uses be uses that lack any or have insufficient crop protection solutions.

The APVMA could also:

- Consider expansion of instances that may constitute reasonable grounds. For instance, one common challenge producers raise with the MUF is accessing new chemistry (uses) where MRL compliance in export markets cannot be achieved through existing registered options. This could be achieved through modification (as underlined) of an existing circumstance to "*Where commodities are <u>either (i)</u> required to be treated with the product or constituent <u>or (ii) lack sufficient registered products</u> to meet particular market access requirements*". This change would also accommodate producers seeking to meet organic production/certification requirements.

- Consider the pursuit of legislative and regulatory provisions through the introduction of incentives and associated guidance to facilitate the registration of minor uses, to lessen the need for producers having to seek minor uses through permits. The MUF would be pleased to provide further comments on suitable initiatives.

- Continue to classify crops as minor and major, although not specifically utilise those as absolute minor use criteria for obtaining a permit but rather simply acknowledge that minor

uses are more problematic for minor crops and affect some uses in major crops. The classification of crops as minor or major is more pertinent to establishing data requirements, and where those should remain commensurate with risk and independent from determinations as to whether a use is a minor use or not (as recommended by OECD refer: https://one.oecd.org/document/env/jm/mono(2009)39/en/pdf).

- Consider the following broad classifications as provided by US EPA (refer: https://www.epa.gov/pria-fees/factors-ir-4-public-interest-finding):
    - a minor crop (≤ 300,000 acres) or a specialty crop, which the 2004 Specialty Crop Competitiveness Act defines to include:
        - fruits;
        - vegetables;
        - tree nuts;
        - dried fruits; and
        - nursery crops (including floriculture); or
    - control of a niche pest on a major crop (where the most likely number of acres treated is ≤ 300,000 acres at the time the application is submitted).

ATTACHMENT 1

The APVMAs discussion paper which supplemented this consultation outlined several suggested factors that may be considered in defining a minor use. The MUF has outlined in the following table and provides comments as to the relevance of each.

It must be noted that these comments are provided in the current context that the existing minor use definition only applies in legislation and practice for the issuance of permits. Should legislative changes occur that expand the application of minor uses to areas of product registration (and chemical reconsideration/review) such as making applications, decisions, fees, timeframes, and data protection then the MUF would be pleased to provide further comments on such suitable initiatives.

APVMA suggested factors	MUF opinions on relevance to defining a minor use
volume of production area under cultivation or numbers of trees or animals	While production figures allow one to differentiate between minor and major crops, minor uses affect all crops, and they cannot be used in isolation as a surrogate for defining a minor use. These figures can be used to classify crops as minor or major for the purposes of determining data requirements to perform appropriate risk assessment but should remain independent from minor use determinations as noted by the OECD (refer: https://one.oecd.org/document/env/jm/mono(2009)39/en/pdf).
dietary consumption	Dietary consumption has no direct relationship to a use being a minor use as defined. These figures can be used to classify crops as minor or major for the purposes of determining data requirements to perform appropriate dietary risk assessment. It is understood that the APVMA guidelines for residue data and number of studies (and crop grouping provisions) are already based on such an approach.
value of crop or animal	The value of a commodity much like area of production (above) has no or little bearing on a use being a major or minor use. Rather high value specialty/minor crops can often be linked to increased liability risk to registrants and are avoided.
export quantities	It is not understood why or how export quantity (or value) would assist in developing guidance for minor uses. Although, they may be used for the purposes of determining data requirements to perform appropriate trade risk assessment. It is understood that the APVMA guidelines for trade assessments already take this into consideration.
pest/disease pressure	It is not clear how this would be utilised for defining minor uses, other than perhaps recognising low prevalence or minor pests/diseases in major crops. The APVMAs current 6A guideline appears to recognise this.

data requirements for registration	Data requirements should remain independent from minor use determinations as noted by the OECD (refer: https://one.oecd.org/document/env/jm/mono(2009)39/en/pdf). It is however true that many minor uses, affecting minor crops that are gown on a small scale are likely to only require smaller data sets when compared to proposed uses in major crops grown over larger areas. Data requirements should be commensurate/proportionate with the level of (new) exposures needing to be assessed.
crop grouping and new registrations	Crop grouping is a proven method of enhancing the registration of minor uses and the MUF supports the work of the APVMA on this. Although, it is not clear how it could be used to define minor uses. While 'rep crops' are often major crops, it is not true for all representative crops or all crop groups. Crop grouping should be based on agreed scientific principles of data extrapolation and where representative crops are selected based on their suitability to cover non-representative crops as required per discipline (ie. residues, efficacy etc.). It is not clear what is intended by 'new registrations'?.
incentives for registration (additional data protection periods)	The MUF notes that the recently introduced provisions for additional data protection does not refer to '*minor use*' and therefore currently the definition would appear not to be relevant. Although the MUF would support further regulatory incentives to enhance the registration of more minor uses would be pleased to provide further comments on suitable initiatives.
market factors	This was not defined in the discussion paper and it is not clear what type of market factors it is referring to?.
global factors – export markets and major trade commodities	Refer above to 'export quantities'.
consumer trends	This was not defined in the discussion paper and it is not clear what consumer trends it is referring to?. However, assuming this is dietary changes to niche or novel foods, ultimately these all begin and many remain as minor uses.
different production methods, e.g. seed production, nursery stock, hydroponics, protected cropping, organic etc.	'Methods of production' are quite similar to defining crops as minor and major, which is not recommended by the MUF for guidance on obtaining a permit for a minor use. The guideline should focus on situations with no or insufficient registered crop protection solutions and that would accommodate for these where and when appropriate.

RE: Updating the guide for determining a minor use - Discussion paper

For many agricultural industries, ensuring compliance in export markets can be problematic due to the lack of, or existence of differing MRLs. Where MRL disparities exist there is little scope for these industries to address the differences by seeking the establishment of import MRLs. This is due such impediments as the cost burden, application requirements, and in some markets the lack of regulatory mechanisms. Where import MRL pathways exist, the cost can be prohibitive, e.g., for the USA the minimum fee to establish an import MRL is US$68,599[1]. For Japan and the Republic of Korea, an import MRL application must be in the respective countries languages[2] coupled with having to address specific data requirements. While for a number of other countries no formal import MRL application process currently exists, e.g., China, Indonesia and the Philippines.

Given these impediments, an alternative approach is needed. The issue could be addressed by the APVMA permitting the use of crop protection products either with approvals or MRLs established in the target export market. Permits granted based on those uses approved in the export destination would help ensure commodities meet export market requirements. Adopting such an approach would also help grow exports in target markets. Nevertheless, as with other permits an application for a 'market access' permit would still need to satisfy the APVMA as to its efficacy and safety but by being based on the importing countries MRL, trade aspects would already be addressed.

The implementation of a 'market access' permit process could be achieved by expanding upon the current Reasonable Grounds test 4.5 (d.)4 as outlined in the 6A Guideline[3], i.e., "*Where commodities are required to be treated with the product or constituent to meet particular market access requirements*", to cover key MRL disparities. Expanding this test would be advantageous for export oriented industries and provide valuable pathway for ensuring export compliance.

Yours sincerely,

[redacted]

[1] https://www.epa.gov/pria-fees/pria-fee-category-table-registration-division-rd-import-and-other-tolerances
[2] APEC Compendium of government administration in setting maximum residue limits for pesticides
[3] 4.5 (d.4) https://apvma.gov.au/node/984

VMDA
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15 June, 2023

VMDA SUBMISSION – UPDATE TO MINOR USE GUIDELINES

The VMDA is a peak body representing the animal health industry in Australia and comprises manufacturers, scientists, regulatory consultants and distributors. The VMDA represents the largest number of manufacturers of veterinary medicines in Australia, as well as many members who source products from outside Australia.

The VMDA supports the concept of the APVMA Minor Use Guidelines to enable vital products to be made available for the treatment of minor species of animals and minor diseases and conditions in all species major and minor.

We support the current guidelines that have allowed for the availability of products in Australia for conditions that, if left untreated, would threaten not only the specific animal or species, but others as well, including humans.

It should be noted that Australia has a wide variety of animal species with consequent diverse diseases and conditions, making it difficult for veterinarians to arrange suitable treatment using approved, properly manufactured therapeutics.

The VMDA looks forward to more details of the proposed review and any changes when made available for further comment, but in the meantime, we wish to make the following points:

Time Frame:
We note that there has not been significant change in these guidelines since the early 2000s, but also point out that time does not necessarily equal the need for dramatic changes. The basic principles of the guidelines are still valid today, especially for animals.

Animal vs Crop:
We support a Minor Use system where animal and crop products are fully separated due to the very different circumstances arising from the use of regulated products including in the food chain.

Compounding:
For many years compounding of veterinary medicines without any significant regulation has been a problem for Australia and has restricted the development of properly formulated safe and suitable medicines for many species. While there has been some progress in proposals to solve some of these problems and to regulate manufacture and supply, there has been no firm outcome in more than 10 years of discussions.

Recognition of a wider need for minor use products would enable our mainstream, fully regulated manufacturing industry to develop products manufactured in approved facilities to assist veterinarians and others in the safe and effective treatment of a range of conditions.

Zoonoses:

Diseases that transfer from animals to humans can be a significant problem, particularly in households with young children (e.g. ringworm in cats) where it is difficult to avoid contact.

In these instances, additional considerations related to human health over and above the 'minor species' definition, and an adjustment to the 'return on investment' criterion, should be considered.

Minor Use Definitions:

The VMDA believes that the definitions of 'minor use' could be expanded to include a consideration of the problem itself, the nature of the active constituents, the method of use of the product, and likelihood (or not) of any adverse outcomes.

Such a change would allow our licensed manufacturers to apply their closely monitored product development and manufacturing skills to providing more safe and effective products for a wider range of conditions for the benefit of our society overall.

The Veterinary Manufacturers and Distributors Association Limited

23 June 2023

Director, Permits and Minor Use
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Submitted via email: enquiries@apvma.gov.au

RE: Updating the guide for determining a minor use Discussion paper February 2023

To whom it may concern,

WoolProducers Australia (WoolProducers) and Sheep Producers Australia welcome the opportunity to provide a submission on the discussion paper, "*Updating the guide for determining a minor use*".

WoolProducers and Sheep Producers Australia are the national peak industry bodies representing Australian wool growers and sheep meat producers respectively. Representation spans a broad range of issues, including, but not limited to animal health and welfare, biosecurity, natural resource management, emergency animal disease outbreak preparedness, market access and assurance and industry development. WoolProducers and Sheep Producers Australia appreciate the role that APVMA plays in regulating AgVet chemicals to support continued safe and efficient agricultural production systems.

WoolProducers and Sheep Producers Australia are satisfied that the criteria for determination of minor use under Schedules 1 and 2 of the "*Guide for determining a minor use"* are reasonable with regards to sheep. Being classed as a *major animal species* within Schedule 1, only schedule 2 is applicable to sheep, whereby classification as a minor use would require less than 10% of the eligible sheep population to be treated per annum.

WoolProducers and Sheep Producers Australia understand that this review is not seeking to inform an amendment of the applicable legislation, however we do believe that the "*Guide for determining a minor use"*, which provides interpretation and guidance on the administration of the applicable legislation, could be amended to better serve the needs to Australian farmers, while continuing to allow the APVMA to fulfill their regulatory functions.

In raising opportunities to enhance the administration of Minor Use Permits, WoolProducers and Sheep Producers Australia wish to draw the APVMAs attention to the Custom R Pilus footrot vaccine, which has been subject to multiple representations to the APVMA, the Department of Agriculture and numerous federal ministers over the past decade. To date the Minor Use Permit pathway has failed to deliver on the needs of Australian wool growers and sheep meat producers in relation to the management and eradication of footrot. The Custom R Pilus footrot vaccine is a serotype specific sheep vaccine that has proven its efficacy and safety under (now unavailable) Emergency Use Permits. The inability to access the vaccine via a Minor Use Permit is continuing to compromise sheep health and welfare, and consequently the sustainability of Australia's wool and sheep meat

industries, owing the current onerous and prohibitive bureaucratic processes associated with permitting and registration of the vaccine.

Availability of equivalent registered product

WoolProducers and Sheep Producers Australia understands that the APVMA has a policy of refusing to grant Emergency Use Permit and Minor Use Permits in instances where 'equivalent' registered products are available. We understand that this policy exists to protect the commercial interests and investment associated with products undertaking the product registration process. This has been the basis for the APVMA refusing to issue either of these two permit types for the Custom R Pilus footrot vaccine.

The APVMA has stated that the serotype-specific Custom R Pilus footrot vaccine is equivalent to the registered Footvax® vaccine (which became available to Australian producers following its successful re-registration in July 2020). The fact is that the assumption of equivalence is ill informed based on outdated assumptions that are no longer fit for purpose (i.e. based exclusively on host x pest). While both products target the footrot (*Dichelobacter nodosus*) in sheep, there are many points of difference between the two products, some of which are listed below:

- The Footvax® vaccine is an 'off the shelf' product that can be accessed and used by producers with little more than a basic visual diagnosis.
- The Custom R Pilus vaccine requires producers to undertake extensive swabbing and serotyping to determine the strains of footrot present in a given flock. This allows determination of the appropriateness to use the custom vaccine and informs formulation to the vaccine to target the strains present within a given flock. The cost of this serotyping often varies between $1500 and $3000, depending on numbers and logistics.
- The Custom R Pilus vaccine, while being limited to one or two serogroups of footrot, has been proven many times (through levy funded research) to have a longer 'effective period' than the Footvax® vaccine.
- The Footvax® vaccine is effective against all serotypes other than M, whereas the Custom R Pilus vaccine can be formulated for various serotype combinations, including M.

Taking the above points into account the Footvax® is a readily accessible broad-spectrum product, whereas the Custom R Pilus vaccine is a specialised product that requires significant producer investment (serotyping) to determine its suitability for inclusion in a control programme.

Schedule 3 - Inadequate determination of "sufficient economic return"

The concept that "sufficient economic return" can be determined with the simple information outlined in the current guidelines is flawed and unlikely to provide sufficient information for the APVMA (a regulator) to reliably distinguish what would yield a sufficient economic return to a commercial entity.

The current considerations within Schedule 3 fail to consider product research and development costs up until the APVMA permit application or registration process commences. With this being the

case, it is not possible to establish what the return on investment is, as the only "investment" costs being considered are the product registration costs.

Schedule 3 fails to take into consideration the opportunity cost to manufacturers or distributors in pursuing full registration. Companies that are willing to pursue products that are of a minor use (as defined by Schedule 1 and 2 of the guidelines) are generally likely be smaller in size and have less resources to support licensing activities and regulatory affairs. As a consequence, such companies need to make decisions as to which products these finite resources are allocated to. These will typically be products that deliver a greater return on investment and are therefore more likely to be excluded from the Minor Use Permit pathway.

Schedule 3 also fails to assess the potential opportunity costs to industry and producers of not having product available to producers. Such costs could be either financial, in terms of decreased production or profitability, or reputational through compromised environmental or animal welfare outcomes. While such costs would not provide a direct return to the manufacturer / distributors of AgVet chemicals, they must be considered when determining "sufficient economic return" at a national level.

The issues above in relation to Schedule 3 assessment criteria will only become more prevalent in the coming years. This will largely be driven by the transition away from traditional broad spectrum and generic chemistry and management approaches to more targeted and bespoke solutions in response to supply chain demands for decreased chemical usage and reduced off-target impacts. With increased usage of these bespoke and targeted products, the current Schedule 3 considerations will only drive AgVet chemicals away from the Australian market, which will obviously lead to undesirable animal health and welfare outcomes and have an overall detrimental impact on Australia's livestock production sector.

WoolProducers and Sheep Producers Australia thank you for the opportunity to provide this submission and look forward to a Minor Use Permit process that better serves the needs of Australian wool and sheep meat producers.

Should you wish to discuss our submission further, please contact WoolProducers' General Manager, Adam Dawes on 0455 442 776, or gm@woolproducers.com.au

Jo Hall
Chief Executive Officer
WoolProducers Australia

Bonnie Skinner
Chief Executive Officer
Sheep Producers Australia