Australian Government

Australian Pesticides and Veterinary Medicines Authority

Public consultation on draft guidelines for determining minor use

Submissions received

October 2024

Animal Medicines Australia
ABN 76 116 948 344 | ACN 116 948 344
18 National Circuit
Barton ACT 2600, Australia
P: +61 2 6257 9022
animalmedicinesaustralia.org.au

11 October 2024

Director, Permits and Minor Use
Australian Pesticides and Veterinary Medicines Authority

By email only: enquiries@apvma.gov.au

Dear Director,

Re: consultation on draft guidelines for determining minor use

Thank you for very much for the opportunity to provide comments on the draft guidelines for determining minor use.

Animal Medicines Australia (AMA) is the industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. They are the local divisions of global innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's $34 billion livestock industry and the $33 billion pet industry. Our members represent more than 90% of registered veterinary medicine sales in Australia.

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. These minor use situations may not provide sufficient economic returns to support a product registration, but effective treatment of affected animals is essential to deliver important animal health and welfare benefits. A minor use permit is a key mechanism to facilitate access and use of important veterinary medicines when there are limited or no registered products available.

AMA notes that the current guidance material is heavily focussed on agricultural applications. 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. In particular, minor uses cannot be approved in one species and extrapolated to others (as is done with crop groups), as physiology and metabolism varies by species. 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 support this work.

The draft guideline includes a proposal to classify salmonids as a major species. AMA has no objection to this change.

The requirement to demonstrate insufficient economic return to consider registration of a product in a major species (thereby justifying the granting of a minor use permit) mandates the use of a Tier 2 PAA. The 2025-26 Cost Recovery proposal (currently also under consultation) includes significant increases to the cost of PAAs, such that a Tier 2 PAA could cost around $3000 (up from $770), with an administration fee of $730 (up from $190). Ther minor use permit itself will cost $500 (up from $350). There are no rebates on registration fees available for PAAs when used to obtain minor use permits. This requirement for a Tier 2 PAA will be a significant deterrent to seeking minor use permits for veterinary uses, thereby encouraging more off-label use to address veterinary needs.

AMA would suggest that a minor use determination for veterinary medicines should not rely on a list of major versus minor species, or economic analyses. The test should, instead, consider whether:

a) there is a genuine need; and
b) there are no suitable or insufficient registered options to meet that need.

In any species, uses that do not meet economic return thresholds are not pursued commercially and are not registered, despite there being an unmet need. If producers identify a particular use as a priority for any animal species, the APVMA should focus on the safety and efficacy considerations to enable that use and issue permits when those requirements are satisfied, not because a particular species is identified as major or minor.

Please let me know if AMA can provide further information at any time.

Yours sincerely,

[redacted]

[redacted]

AUSTRALIAN OLIVE ASSOCIATION

ABN 57 072 977 489 ACN 072 977 489

PO Box 3012
Allambie Heights LPO
ALLAMBIE HEIGHTS NSW 2100
Office: 0476 760 160
International: +61 4 7676 0160

Email: ceo@australianolives.com.au
www.australianolives.com.au

11 October 2024

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

Via email: enquiries@apvma.gov.au

Dear Director for Permits and Minor Use,

Re: Draft Guidelines for Determining Minor Use

The Australian Olive Association Ltd (AOA) is the prescribed industry body representing all olive growers, service providers and processors in Australia. The Australian Industry estimates that there are around 450 commercial olive groves covering more than 33,000 hectares, with 75 per cent of the olive trees concentrated in 20 groves. Our membership, while predominantly Australian, also comprises international growers, processors and industry participants.

AOA has the following comments regarding the proposed guidelines regarding minor use. These comments relate specifically to olives and the olive sector. The information provided in this submission is intended to assist the APVMA in developing a set of well-defined parameters regarding classifying olives (in our view) as a minor crop.

1. Proposed Changes to the list of Major Crops:

Olives have been added to the proposed new list of Major Crops in Group 005 Assorted Tropical and Sub-Tropical Fruit – Edible Peel. The grouping of olives in Assorted Tropical and Sub-Tropical Fruit is incorrect as olives are a Mediterranean tree which grow best in non-humid environments away from tropical and subtropical areas. The major commercial groves are located in inland New South Wales, Victoria, South Australia and Western Australia where irrigation is available, but the air is dry.

Botanically, olives are a drupe, a fleshy fruit with a thin skin and a central stone or pit containing the seed – just like cherries, peaches, apricots and other stone fruit.

The criteria for determining a major crop are based on current statistics regarding volume of production, numbers of trees and the value of the crop.

It is our view that olives do not meet the criteria for a major crop for the following reasons:

- Production area of olive trees (at about 33,000 ha) places olives as a major crop according to the proposed new guidelines. However, 70% of olives are produced by one major grower with 2.5 million trees. This means that there are many smaller groves are not being run commercially to full potential. So, the number of olive trees in Australia is not a good indicator of the industry size or value.
- Production volume is not a relevant measure to determine olives are a major crop because 97% of all olives harvested in Australia are processed into olive oil (oil yields can range from <10% to 25%), mostly within 6 hours from harvest to maintain the highest level of olive oil quality (Extra Virgin Olive Oil). This requires commercial growers to also be processors and to invest in the capital equipment to harvest and process the olives in the same day. This is one reason why many smaller groves are not productive nor profitable.
- With olive trees being biennial bearing (years alternating with high and low yields) plus the price of olive oil being determined by global prices – Australia only produces about 50% of the demand for olive oil here, the rest is imported – the value of production fluctuates significantly from year to year. The draft guidelines referred to ABS statistics indicating there are over 6 million olive trees with a production value of $120 million which the guidelines say is comparable in scale and value with other major tree crops. However, AOA disputes this when a project completed by the Centre for International Economics with funding from Horticulture Innovation Australia, *Economic Contribution of Australian Horticulture*, shows that the value of Australian olives is much less than estimated for other major tree crops:

Tree Crop	Production Value (2023) $million
Olives	**120**
Cherries	198
Apricots, plums, peaches, nectarines	227
Mandarins	235
Oranges	269
Almonds	453
Apples	478

Source: https://www.horticulture.com.au/growers/help-your-business-grow/research-reports-publications-fact-sheets-and-more/mt21010/

- Mushrooms have been proposed in the guidelines for removal as a major crop even though they have an estimated production value of $196 million in 2023 because the cost of data generation means registration of many crop protection products would not provide sufficient economic return to a registrant. This applies equally to olives which would not be able to afford the registration costs of chemicals if categorised as a major crop.

2. Limited Use

The Australian olive industry produces less than 1% of world olive and olive oil production. This makes our industry very undesirable from an economic point of view for multinational chemical companies to invest in registration of chemicals for olives in Australia.

The minor use system is important for our industry because it provides cost effective and timely access to vital chemicals for olive tree protection as and when needed. The olive industry is very focussed on sustainability and promotes itself as a net carbon sequestering industry. The industry promotes the use of integrated pest and disease management where chemical use is one of several options promoted to growers to protect tree health and yields. Therefore, the olive industry is not a major user of chemicals but will use them when required in a targeted way.

The olive industry also supports the berry industry in their submission for the development of clear, quantitative guidelines around what constitutes minor use based on a firm understanding of scale, value and other factors contributing to market failure where a crop is not economically viable for the chemical companies and the growers to invest in registration.

Along with the berry industry we would like to have further discussions with the APVMA, the crop protection product providers and Hort Innovation to identify innovative approaches to overcoming market failure using minor use permits and other potentially untapped tools. If costs and resources are a significant constraint to APVMA in managing minor use, the olive industry would be happy to work with APVMA and HIA in developing systems that are more efficient and cost effective.

As Australia is involved with the Minor Use Foundation with DAFF being a partner, the olive industry would support APVMA in seeking ways to tap into work being done internationally to support minor crops which may not be commercial giants but have a very important role in the health and nutrition of people across the world. Extra virgin olive oil underpins the well-known health benefits associated with a Mediterranean diet; these health benefits include protection against inflammation, cardiovascular disease, cancer and cognitive decline and are well documented in scientific literature.

AOA does not consider olives to be a major crop based on the criteria in the proposed minor use guidelines and current statistics on crop value.

Chemical use by the Australian olive industry is low and would not be attractive to chemical companies for investment in chemical registration.

AOA welcomes further discussion with APVMA to explore minor use issues and to ensure that minor crops are not disadvantaged by a new regulatory system.

I welcome further discussion on this subject and if you require any other information, please contact me.

Yours sincerely,

AUSTRALIAN OLIVE ASSOCIATION LTD.

Michael Southan PhD
CHIEF EXECUTIVE OFFICER

10 October 2024

To: Australian Pesticides and Veterinary Medicines Authority (APVMA)

Re: Public Consultation on Draft Guidelines for Determining Minor Use

Australian Organic Limited (AOL) appreciates the opportunity to provide feedback on the Draft Guidelines for Determining Minor Use. On behalf of Australia's certified organic sector, we wish to highlight several concerns regarding the proposed changes, particularly the reclassification of certain crops and the financial burdens associated with Major Use Permits.

Australia's organic sector, while steadily growing, remains a niche industry that requires continued strategic support to maintain its momentum. Despite Australia accounting for nearly half of the world's organic farmland, its contribution to the global organic industry remains limited at just 1% of the estimated $330 billion market[1]. This disparity highlights the unique challenges faced by Australia's organic producers, including restricted access to essential inputs and biosecurity tools, which are crucial for maintaining certification and competitiveness.

The Australian organic industry is currently valued at $2.6 billion, with 3,035 certified organic businesses supporting over 22,000 full-time equivalent workers[2]. However, due to limited market access and restrictions on inputs, organic farmers may often face higher production costs and significant challenges in managing pests and diseases. Organic producers prioritise soil health and proactive management strategies to manage agroecosystems; however, when this is insufficient, organic certification standards impose strict requirements on allowable inputs, limiting the options available for treating pests and disease incursions. Consequently, organic farmers rely heavily on Minor Use Permits to access biosecurity tools that help maintain production while adhering to organic standards. Without these permits, organic farmers would struggle to treat pest and disease incursions effectively, putting their livelihoods and organic certification at risk.

Despite growing consumer demand and positive market trends[3], the organic sector remains a minority industry in Australia's agricultural landscape. Consequently, Minor Use Permits and other cost-effective options are crucial for organic farmers to continue producing across all categories while maintaining certification and sustainability standards. The proposed reclassification of crops, as well as the financial burdens associated with obtaining Major Use Permits, could have lasting effects on the organic sector. Below are our key concerns regarding these changes:

[1] https://www.precedenceresearch.com/organic-food-market
[2] ACIL Allen, Mobium Group, & NielsenIQ. (2023). Australian Organic Market Report 2023. Australian Organic Limited.
[3] https://www.forbes.com/sites/earlcarr/2024/03/29/trends-in-organic-food-consumption-redefining-esg-in-regenerative-agriculture/

1. Impact of Crop Reclassification on Organic Growers

The reclassification of crops such as lemons, cucumbers, zucchinis, olives, raspberries, and blueberries from "minor" to "major" raises significant concerns for organic growers. Historically, organic farmers have relied on Minor Use Permits to access specific inputs that are otherwise unavailable due to the strict requirements of organic farming. The proposed reclassification of these crops as major could limit the availability of Minor Use Permits, leaving growers without the necessary tools to treat pests and diseases effectively while adhering to organic standards.

This creates a particular challenge for organic farmers, as they must balance the need for pest treatment with the expectations of the broader organic community, which demands strict adherence to organic principles. Minor Use Permits have historically provided a more cost-effective pathway for accessing registered inputs that aligns with organic practices without compromising the sector's commitment to organic farming principles. Notwithstanding, the initial Major Use registration of inputs with the APVMA remains an extremely cost-prohibitive process for smaller businesses pushing sustainable innovation, and there remains an opportunity to improve this process.

The reclassification of these crops without sufficient consultation with key agricultural and organic industry representatives risks introducing significant challenges for growers across multiple sectors. A more thorough engagement process is necessary to fully assess the potential impacts on both organic and non-organic farming systems.

2. Financial Challenges and Regulatory Burden for Allowed Input Operators

Allowed Input operators, who supply inputs such as organic-approved pest control products to organic farms, already face prohibitive costs, particularly when meeting the stringent Health, Safety, and Environmental assessment requirements, which are among the most expensive in the APVMA's registration process[4]. While we understand these assessments are crucial for ensuring product safety and efficacy, the cost burden falls disproportionately on smaller organic input suppliers, limiting their ability to develop and register products for the organic market. Given that a significant proportion of organic producers are small to medium-sized businesses, these rising costs further hinder their ability to operate sustainably and access the necessary inputs to meet organic certification standards.

[4] https://www.apvma.gov.au/registrations-and-permits/chemical-product-registration/timeframes-and-fees

As the process for obtaining a diversified applicability of input products becomes more expensive, there is great concern that suppliers will no longer find it economically viable to develop and sell products specifically for the organic sector. This not only reduces the availability of inputs for organic growers but also impacts innovation within the organic farming industry. Furthermore, the increasing regulatory and data requirements disproportionately affect smaller producers, creating additional challenges in accessing critical inputs. Simplifying the application process and reducing unnecessary regulatory burdens would allow more organic producers to continue operating sustainably while maintaining high safety and environmental standards.

3. The Need for Organic Farming to Be Recognised as a Distinct Sector

Despite the industry's small size and different operational needs, the draft guidelines do not formally recognise organic farming as a uniquely different sector from non-organic farming. This lack of recognition creates a situation where the requirements of organic producers are not considered "minor use." Unlike other sectors such as protected cropping, organic farming operates under strict rules and limited input availability, making it essential to have access to a flexible system that recognises effective products without the additional financial and administrative burdens of getting Major Use Permits.

Request for Formal Recognition

AOL urges the APVMA to classify organic farming as a distinct category under the APVMA registration to recognise the importance of prioritising softer yet effective inputs. This recognition would allow organic growers to continue accessing essential inputs through more cost-effective schemes like Minor Use Permits, ensuring that the sector can maintain its rigorous standards while meeting biosecurity and production challenges.

Conclusion

The sector's primary concern is the proposed reclassification of key organic crops from "minor" to "major," which threatens to limit organic producers' access to affordable allowed treatments. We strongly urge the APVMA to reconsider this reclassification, as it could have significant consequences for the ability of organic farmers to treat pest and disease incursions while maintaining certification standards.

Additionally, we request that the APVMA address the financial challenges faced by the organic industry in navigating the full product registration process. The extensive and expensive requirements for registering products, such as gathering efficacy, safety, and residue data, disproportionately impact the organic sector, which, as a minority industry, often lacks the

resources to absorb these costs. Without more accessible registration pathways or cost-effective solutions, organic producers will struggle to access the critical biosecurity tools needed to sustain their operations and meet growing consumer demand for certified organic products.

Proactive management is always preferred, but in cases where treatment is required to comply with biosecurity requirements, organic farmers must have access to registered tools. However, if the cost of registering these treatments remains prohibitively high, producers may find themselves unable to meet both biosecurity and organic certification standards. Addressing these challenges is essential to ensuring that the organic sector can comply with official biosecurity measures while continuing to operate sustainably.

We encourage the APVMA to explore options that balance safety and environmental concerns with the economic realities faced by the organic sector, ensuring that it can continue to thrive and meet the increasing demand for organic products.

Finally, we reiterate our call for the formal recognition of organic farming as a distinct sector under the Minor Use Guidelines. This recognition would ensure that organic producers continue to have access to necessary inputs while maintaining the sustainability and integrity of the organic farming system.

Thank you for considering our feedback. We welcome further discussion and remain committed to collaborating with the APVMA to ensure the needs of the organic sector are adequately addressed in the final guidelines.

About AOL

Australian Organic Limited (AOL) is the peak industry body for the organic industry in Australia that strives to create a positive impact for humans, animals, and the environment, now and into the future. AOL is led by an experienced team committed to progressing the interests of the organic sector and delivering a world where organics is recognised for its environmental, social, and economic benefits.

TASSAL GROUP LIMITED
ABN 15 106 067 270
GPO Box 1645, Hobart, TAS 7001

1300 660 491

tassal@tassal.com.au
tassalgroup.com.au / tassal.com.au

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

Dear Director,

Tassal Group Limited welcomes the opportunity to provide its views in relation to the development of the 'Draft Guidelines for Determining Minor Use' by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Summary

1. Tassal Group Limited opposes the proposal to list Salmonids as a major species. Salmonids should remain a minor species;
2. Tassal Group Limited recognises that its other farmed species have not been proposed for major species status and we support this position;
3. Tassal Group Limited considers that a proposal to list salmonids as a major species has deep and counterproductive outcomes, and that the "Draft Guidelines for Determining Minor Use" lacks detail and clear, transparent, consistent reasoning in the reassignment of this animal group. In short, such a significant regulatory impost has not been adequately reviewed and assessed for its impact;
4. The salmon farming sector is subject to the most number and depth of regulatory instruments of any farming sector in Australia, on top of which we do not see any significant volume growth going forward. The well-being of the sector depends on margin improvement and cost control. This proposal increases cost with no discernible change to the safety and efficacy of the products we use. In fact, it would result in poorer welfare outcomes and increased cost.
5. In general principles, where a group is proposed to move from minor to major, the consultation must also include details of transitional processes to avoid catastrophic effects, such transitional periods to reflect the time taken to develop data for products including storage stability etc., followed by regulatory assessments, for example in total four to five years. During this period permits must issued for the duration of the transitional period so there

is certainty of supply and use. If during the transitional period, there is evidence that the decision to move a species group was incorrect and adverse impacts are apparent, then the process must be reversed.

Preface

6. The ability to access safe and effective veterinary medicines is critical for the salmon industry. It ensures the health and welfare of our fish and the delivery of a premium product to our customers;
7. The salmon industry is particularly vulnerable to health and biosecurity risks given the environment it operates in and is particularly subject to the actions of biosecurity risk exacerbators;
8. Industry only has a an extremely limited range of products available to manage those risks (including those currently used under a 'minor use permit' MUP);
9. Further restricting the available options to the salmon industry by making registration necessary, or the process of acquiring MUPs more onerous and time consuming would be detrimental to the industry and affect the health and welfare of fish;
10. Veterinary medicine use in salmon is very different to that of terrestrial animals and all products within our industry are currently used as minor applications or under veterinary prescription. This is due to sporadic use, use only at certain sites or situations, small volumes used, small numbers of fish used on, or products that are regularly refined and updated;
11. The salmon sector has responsibly and proactively invested in the development of many of our own solutions, recognised through APVMA systems and to increase the costs of achieving approvals, when products already achieve acceptable standards would simply inhibit this proactive approach.

Determination of a minor use (page 3)

12. We note that a significant determinant of minor use of a product is where there would reasonably be expected to be a failure to provide sufficient economic return (addressed below);
13. We note the other reasons for considering a use minor, and whilst it has been indicated that a major species can still have minor use and that some are applicable, our main welfare tools are by design applied to all animals and thus would not meet those clauses other than that of not producing sufficient economic return;
14. We argue that all our veterinary tools would meet this concept of insufficient economic return; however, having to demonstrate this at every application simply adds cost and reduces further the chances of suppliers wishing to get involved in servicing the salmon sector;

15. The change to make salmon a 'major' species would not achieve any practical or beneficial outcomes for the salmon industry, its manufacturers or suppliers. It instead creates an administrative and financial burden on the industry's suppliers as almost every product the industry currently uses will need to be retained under a MUP because of the insufficient economic returns to register. It is a great concern for the industry that the need to repeatedly justify and furnish all the necessary information to satisfy Section 3 of the guidelines every time a MUP or renewal is required, could deter suppliers from considering MUP's for their products. This could lead to a situation where there are no Registered products available, and no products available under MUPs either.

Guidance key to eligibility for minor use (page 3)

16. The guidance key is straightforward and understandable;
17. We note the reference to 'sufficient economic return' and intend to discuss this further under Section 3 commentary below.

Section 1 – Major crops, animals and situations (page 4)

18. We oppose the listing of salmonids as a major species in Section 1 (page 6) and we will outline our reasoning for this in clauses 24 to 30 below.

Section 2 – Limited use within a major crop, animal or non-crop situation (page 7)

19. The limited use matrices for veterinary products have no suggested values for salmonids, so it is hard for an industry to assess the risks and impacts clearly for the suggested listing as a major species. It is not acceptable for such a major change to be suggested without having thought through all the aspects of the discussion paper and providing clear details to comment on, particularly in relation to the potential addition of a species group to the major list;
20. In addition, the production quantities and values listed as trigger levels in the table are low in current terms and need re-assessed.

Section 3 – Insufficient economic return

21. It is unclear from the document what quantum of economic return is considered 'sufficient'; it must be a quantum above break-even or there is no driver for a commercial manufacturer to get involved in production;
22. Given the costs involved in the development of, for example, the salmon sector's two main vaccines, and the historical situation where those vaccines are being continually researched and subject to regular changes to

accommodate new antigens, changing antigens (identified through the industry proactive vaccine evasion surveillance projects), and other recipe improvements, such as dose, adjuvant volumes and adjuvant types, we have estimated according to the formula on page 10 that simply to break-even would be 30% of the vaccine cost. For a manufacturer to be interested there needs to be a significant margin above that;

23. This is simply due to the bespoke and low volume nature of the vaccines – that will not change moving forward, and it is best to recognise that upfront and simply retain the species group and its products as minor.

Appendix A and Appendix B (pages 13 to 19)

24. This section lists proposed changes to the major species list with little to no detailed, consistent analysis; no rubric to guide an assessment or provide opportunity for affected parties to understand the critical data that has been used;
25. When a species is being de-listed, perhaps a more cursory assessment is suitable, but for a species proposed to be listed at major for the first time, and with the increased regulatory burden attached to that, it requires a more robust, transparent method than that outlined in this consultation document which was simply 6 lines of rather subjective commentary, mainly focused on a volume growth over 10 years – the reality is that we foresee no significant growth in volume, and that volume (as indicated below in clauses 27 to 29) is small compared with other animal proteins in Australia;
26. Appendix B sets out some brief reasons ('Notes on selected commodities') for changes to species groups and those have been read and compared in an effort to assess to some extent reasoning for a change from major or minor and thus vice versa;
27. It is our contention that salmon is a minor species when compared against the other animal species:
    a. The volume share of fresh protein in Australia is 38.2% chicken, 24.9% beef, 17.8% pork, 7.4% lamb and 1.2% salmon;
    b. Beef produces 2,250,000mT, pork 480,000mT, lamb 621,000mT, chicken 1,256,000mT, whereas salmon produces 82,000mT, a quantum less;
28. In addition, the apparent reasoning behind moving certain groups from major to minor must be considered and the decision as regards salmonids assessed in light of the indicators in those cases:
    a. Pineapples and mushrooms are two groups slated for movement to minor listing;
    b. Reasoning included relatively high-value low volume, few growers and limited cropping area;
    c. These arguments also apply to salmon – a sector of low volume (compared to other animal proteins), just three growers and limited growing areas geographically restricted – the combined surface areas of our pens amount to just over 100 hectares; compared to mushrooms at 132 hectares;

HOBART
Level 9, 1 Franklin Wharf,
Hobart, Tasmania 7000
Telephone (03) 6244 9099
Facsimile (03) 6244 9002

MELBOURNE
Level 2, 1-9 Derrick Street,
Kew, Victoria 3101
Telephone 1300 66 4731
Facsimile 1300 88 1429

HUONVILLE
20 Glen Road,
Huonville, Tasmania 7109
Telephone 1300 66 4251
Facsimile 1300 88 0239

SYDNEY (De Costi Seafoods)
29 Bachell Avenue,
Lidcombe, NSW 2141
Telephone (02) 9649 7699
Facsimile (02) 9649 7655

d. To add some more context these proposed minor species produce over 70,000mT each and mushrooms are consumed by the Australian public at a rate 50% higher than salmon (3kg per capita per year)

29. It is also critical to realise that many products can be used across a number of species groups in horticulture and veterinary medicine e.g. the same products may be used in ruminants and pigs for example, thus the effective scale of production for those products are much larger than the individual species production volumes themselves. The same is not true in the case of salmonids; we use different compounds in general.
30. Given the above comparisons, the overwhelming evidence points to salmon being a minor species.

Please do not hesitate to contact me if you require further information.

Kind regards,

Colin Johnston

Chief Technical Officer

HOBART
Level 9, 1 Franklin Wharf,
Hobart, Tasmania 7000
Telephone (03) 6244 9099
Facsimile (03) 6244 9002

MELBOURNE
Level 2, 1-9 Derrick Street,
Kew, Victoria 3101
Telephone 1300 66 4731
Facsimile 1300 88 1429

HUONVILLE
20 Glen Road,
Huonville, Tasmania 7109
Telephone 1300 66 4251
Facsimile 1300 88 0239

SYDNEY (De Costi Seafoods)
29 Bachell Avenue,
Lidcombe, NSW 2141
Telephone (02) 9649 7699
Facsimile (02) 9649 7655

[redacted]

[redacted]

To the Director, Permits and Minor Use,

Please find below a summary of feedback to the 'Draft Guidelines for Determining Minor Use, Public Consultation'.

Regarding the 5th bullet point on page 9, I am uncertain that it is reasonable for the applicant to provide 'evidence' of alternatives that do not exist, especially as APVMA would be aware of registrations on the APVMA's own database. A solution could be to re-word the requirement such that the onus is on the applicant to ensure there are no other alternatives.

The structure and wording in Section 3 is sometimes unclear for example,

- The first sentence 'When registration would…' is incomplete. Or is this intended to be a header?
- In reference to the paragraph commencing 'Ordinarily, we will….' through to the paragraph ending '….approved active constituent.'; the breakdown of points 1. and 2. is an unnecessary distraction from the intent of these two paragraphs.

The PAA steps to take in Section 3 are unnecessarily exhaustive and would need significant resources and would seem to me to be a paradox given the intent of the applicant is to demonstrate insufficient economic return. Furthermore, this would only encourage businesses to cease manufacture of products which are not economically profitable, rather, are being continued for reasons of good intentions whether it is supporting the Australian economy, supporting government initiatives, social responsibility, sustainability or human and animal well-being.

Regarding projected costs, any forecasting beyond 12 months is difficult for most businesses. Our industry, in particular, is susceptible to many unpredictable factors e.g. environmental, government policy, disease. In our opinion, it is therefore unreasonable to expect a minimum of 3 years forecasting.

Feel free to contact me for clarifications.

[redacted]

11 October, 2024

ABN: 25 107 507 559
ACN: 107 507 559
3 Glenarm Rd
Glen Iris VIC 3146
T (03) 9882 0277
E info@ausveg.com.au
www.ausveg.com.au

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

Re: Draft Guidelines for Minor Use

AUSVEG welcomes this opportunity to comment on APVMA's draft Guideline for Determining Minor Use. AUSVEG, as the industry body representing the vegetable production sector, and has consulted industries potentially affected by the proposed regulatory decisions. This has resulted in concerns being raised over a number of recommended regulatory actions.

AUSVEG is aware that APVMA have received submissions from other grower bodies flagging concerns over the recommended actions. It of critical importance to consider the following when making regulatory decisions for our industry:

Introduction to AUSVEG

AUSVEG is the national peak industry body representing the interests of Australian vegetable, potato and onion growers, an industry valued at $5.5 billion contributing to food and job security in the Australian economy. We are committed to securing the industry's future.

We advocate for growers, to all levels of government and ensure that the industry has a strong, active voice in the public sphere. We also communicate industry issues and perspectives to government, media and the public.

AUSVEG acknowledges the important role the APVMA plays in ensuring that chemicals sold in Australia are safe and effective. We support a strong, science based regulatory system for agricultural and veterinary chemicals. However, critically, timely access to modern crop protection products is vital for a robust and competitive agricultural sector and the regulatory system needs to be an enabler of access to appropriate chemistry, not an inhibitor.

AUSVEG has a number of concerns to the draft over aspects of the APVMA's draft Guideline for Determining Minor Use.

Disappointingly, it appears the APVMA has placed little weight in the submissions made to the 2023 consultation. In particular, the draft guidelines have done little to address issue relating to need, and focused primarily on classifying uses and crops on threshold levels

based on value and acreage. Outlined below are the specific issues AUSVEG believes need further elaboration by the APVMA.

1. **Determination of threshold levels**. The Guideline provides no reasoning or justification for the threshold levels used in the classification matrix. It would be important to understand how the cut-off levels for the low, medium and high were determined. Given the bearing these classifications have on the nature of an application, e.g., information requirements, AUSVEG believes the APVMA needs to provide more detail on the basis for these thresholds. Without such information it is impossible for stakeholders to provide meaningful feedback as to their applicability, or otherwise.

2. **Determination as a major crop**. Linked to the above, AUSVEG seeks clarification on the basis for designating certain vegetable crops as major. For a number of crops, it appears an important factor in being classified as major, is that they have been identified as representative crops. It is the understanding of AUSVEG that while the commercial importance of a crop is relevant in selecting representative crops, the key determinant is the residue characteristics of the crop, and that this needs to be similar to other members of the group or subgroup. As a result a representative crop may not in fact be 'major'. AUSVEG is concerned that the classifying certain representative crops as major, will significantly impact data requirements, place significant additional administrative burden on the applicant to prove minor use and further impede chemical access. For example, the current APVMA guidance on residue trial numbers indicates 8-12 trials for major crops, 4-6 for minor-major crops (presumably those crops falling into the "*More information required*" category[1]) and two trials for minor crops[2]. A change from minor, or minor-major, to major will cause a significant cost increase from the perspective of data generation to gain, or retain APVMA approvals.

   We support development of clear, economic based guidelines to determine which crops and uses can be considered minor or major based on the need to overcome market failure.

3. **Renewal of current minor use permits.** AUSVEG asks whether the APVMA has given any consideration to the potential impacts of the new classifications going forward, e.g., on possible renewals for current minor use permits? An interrogation of the APVMA permit database found that there are currently in excess of 250 permits relating to vegetable crops. Of these approximately half cover multiple vegetable crops. While all are not minor use permits, the majority are. Given that number, has the APVMA undertaken any analysis of the likely impact the new matrix thresholds and crop classifications might have on future permit renewals, or considered how the renewals process is to be managed in the future? Having such an analysis and outline would give stakeholder industries a clearer grasp of the magnitude of issues

[1] Table 1 Classification of minor uses Draft Guidelines for Determining Minor Use 2024

[2] https://www.apvma.gov.au/registrations-and-permits/data-requirements/agricultural-data-guidelines/residues-part-5a/specific/residue-trials-permanent-mrls

in the future. To illustrate this point see the Table below, providing a listing of current permits and registered options by pest management problem for celery.

Problem	Permit No	Active constituent (MoA)*	Registered active constituent (MoA)
Aphids	PER12489	Imidacloprid (4A)	Afidopyropen (9D), malathion (1B), pirimicarb (1A), pymetrozine (9B), spirotetramat (23), sulfoxaflor (4C)
Light brown apple moth	PER88066	Emamectin (6)	
Cluster caterpillar	PER88066	Emamectin (6)	Diazinon (1B), indoxacarb (22A)
	PER82428	Methomyl (1A)	
	PER12221	Petroleum oil (UNM)	
Helicoverpa	PER82358	Esfenvalerate (3A)	Chlorantraniliprole (28), diazinon (1B), esfenvalerate (3A)#, flubendiamide (28), NPV (31), permethrin (3A), spinetoram (5), spinosad (5)
	PER88066	Emamectin (6)	
	PER82428	Methomyl (1A)	
Leaf miner	PER93850	Cyantraniliprole (28)	
	PER94854	Isocycloseram (30)	
	PER88640	Spirotetramat (23)	
Lucerne leaf roller	PER14843	Indoxacarb (22A)	Esfenvalerate (3A), permethrin (3A)
RLEM	PER86599	Bifenthrin (3A)	Malathion (1B)
Thrips	PER83203	Fipronil (2B)	Malathion (1B), spirotetramat (23)
	PER82428	Methomyl (1A)	
	PER12221	Petroleum oil (UNM)	
	PER12489	Imidacloprid (4A)	
Whitefly	PER82467	Buprofezin (16)	Afidopyropen (9D)
	PER12489	Imidacloprid (4A)	
Anthracnose	PER93212	Cyprodinil (9) & fludioxonil (12) & Pyraclostrobin (11)	Thiram (M3)
Septoria	PER13673	Metalaxyl-M (4) + Mancozeb (M3)	Chlorothalonil (M5), copper (M1), difenoconazole (3), difenoconazole (3) + pydiflumetofen (11), mancozeb (M3), metiram (M3), propineb (M3), thiram (M3), zineb (M3), ziram (M3)
	PER14479	Propiconazole (3)	
Sclerotinia	PER11127	Boscalid (7)	Iprodione (2)

* MoA Mode of action group

Recent Permit to label addition

From the above it can be seen that the purpose for seeking permits has been to fill pest management gaps, i.e., the need to access additional control options. Access to minor use permits has been critical from the perspective of maintaining viable celery production. For celery growers it is now unclear how the crop being classified as a major crop will impact renewals future applications. We understand the burden of proof of minor use will be significant. Or will existing minor use permits now be refused when renewal is sought, due to the change in classification?

AUSVEG recommends that any change in minor status of a crop should be accompanied by a significantly extended transition period developed in consultation with the affected industry to ensure that there isn't a gap of available ag vet solutions for the industry.

AUSVEG therefore believes that with the current draft Guideline, the APVMA has missed an opportunity for meaningful reform to the Guidelines, to better reflect the nature of

problems relating to chemical access in Australian agriculture. While recognising the legislation references insufficient economic return it is difficult to see how focusing on crop value or acreage addresses this requirement. The fact that many crops, major and minor, currently lack sufficient registered options for endemic pest, disease and weed problems should act as a significant indicator to alert the APVMA to the fact that for many uses registrants have had little or no interest.

Consequently, AUSVEG believes there needs to be greater emphasis on exploring mechanisms on how to more effectively manage minor use pest management needs. For example, AUSVEG notes the positive outcomes achieved through the Permit to Label project and that the APVMA has stated the agency is *"now exploring ways to incorporate the permit-to-label process into our core business in the future*"[3]. In that context further engagement with stakeholders in the development of such initiatives, coupled with the provision of more detailed guidance around what can be considered a minor use would serve to create a minor use permit system that was more efficient and effective from the perspective of both the agency and user groups.

In summary, AUSVEGs recommendations are:

- Clear guidelines for determination of a major and minor crop based on robust economic modelling.
- Extended transition period and clear plan when there is a classification change from minor to major.
- That based on the concerns, APVMA i pause their intent to implement the proposed "guidelines".

Yours sincerely,

Zarmeen Hassan
National Manager Engagement and Extension

[3] https://www.apvma.gov.au/registrations-and-permits/chemical-product-registration/permit-to-label-project

Guidelines for determining a minor use
APVMA consultation

Submission of the
Australian Veterinary Association Ltd

October 2024

www.ava.com.au

The Australian Veterinary Association (AVA)

The Australian Veterinary Association (AVA) is the national organisation representing veterinarians in Australia. The AVA consists of members who come from all fields within the veterinary profession. Clinical practitioners work with companion animals, horses, farm animals, such as cattle and sheep, and wildlife. Government veterinarians work with our animal health, public health and quarantine systems while other members work in industry for pharmaceutical and other commercial enterprises. We have members who work in research and teaching in a range of scientific disciplines. Veterinary students are also members of the Association.

Background

The APVMA has requested stakeholder input in relation to the proposed 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.

Proposed guidelines

The proposed guidelines appear to be designed mainly for use for agricultural chemicals rather than veterinary chemicals. Most permits are issued for agricultural chemicals so it is reasonable that the guidelines are better suited to agricultural chemicals, however it should be recognised that there is a need for minor use permits for veterinary chemicals.

An earlier submission from the AVA was sent to the APVMA in June 2023. In this submission was a proposal that the 'minor use permit' include low value products as currently there is 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 for low value products. There is an increasing use by veterinarians of compounded veterinary medicines, which require no registration. As a result, there is a disincentive for new product registration.

If minor use permits can be issued for low value products this would allow sales and income revenue during the lengthy registration process and provide an avenue for registration of new products.

The proposed guidelines do include low value products -

> "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)."

In theory it should be possible to obtain a minor use permit for the type of product proposed in the earlier submission within the scope of the proposed guidelines.

However currently it appears that obtaining a minor use permit requires similar technical assessment to obtaining a product registration.

The APVMA website includes the below statement in relation to permits -

> "The statutory criteria that must be satisfied in order for the APVMA to issue a permit is similar to an active constituent approval or a product registration."

This implies that the same amount of information is required for a permit that is required for a full registration. If this were the case, then there would be no need for a minor use permit.

It is apparent that as well as reviewing the guidelines for determining a minor use the APVMA should review the requirements for a minor use permit which has not been covered by the current review of the guidelines.

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 label 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.

The AVA encourages the APVMA to also review the requirements for obtaining a minor use permit and not just the guidelines for determining a minor use. Currently it is very difficult to obtain a minor use permit, the development of clear guidelines for approval of minor use permits would assist registrants to understand what information is required, encourage registrants to apply for minor use permits for low value products and streamline the process for minor use permit approval. This would hopefully result in more registered products being available for use by Australian veterinarians rather than having to rely on using compounded veterinary medicines and the associated risks of using unregistered products.

Contact:

Graham Pratt
National Manager, Advocacy & Divisions
Australian Veterinary Association
[redacted]

Berries Australia Limited
ABN 48 627 401 692
PO Box 578 Archerfield, QLD 4108
Telephone: 1300 201 713 Mobile: 0408 796 199
Email: rachelmackenzie@berries.net.au

11 October 2024

Director, Permits and Minor Use
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001
Via email: enquiries@apvma.gov.au
Cc: Scott.Hansen@apvma.gov.au

To whom it may concern,

Berries Australia submission on the APVMA's Draft Guidelines for determining minor use.

Berries Australia was established in November 2018 as a joint venture between the Australian Blueberry Growers' Association Inc. (ABGA), Raspberries and Blackberries Australia Inc. (RABA) and Strawberries Australia Inc. (SAI) to represent the interests of the Australian berry industry as a whole. Whilst the value of the Australian berry industry has grown significantly in the last twenty years, globally we are a relatively small player with limited export access. Traditionally berries were only grown in cooler regions, however significant investment in varietals means that berries are grown from Tasmania to the Atherton Tablelands. This geographic diversity means we can produce all year round, but it does bring a unique set of pest and disease management challenges.

Overview

Berries Australia is a strong supporter of a rigorous science based regulatory system for agricultural and veterinary chemicals. APVMA plays an important role in ensuring that chemicals sold and used in Australia are both safe and effective. At the same time, timely access to modern crop protection products is vital for the international competitiveness of Australian agricultural produce, meaning the regulatory system that underpins it, needs to be an enabler of access to appropriate chemistry, not an inhibitor.

It is a statement of fact that Australia is a relatively small market globally in terms of agricultural chemicals, and this means our system must compensate for the lack of return on investment for chemical companies to ensure our growers are not left behind. The minor use system is vital for the horticulture sector because it ensures cost effective and timely access to vital crop protection products, thereby providing an effective way to overcome the barrier of being a minor crop, which by definition lacks economies of scale, and in what is already a small market globally.

Berries Australia supports the existing definition of a minor use 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 the registration of the product*". This is essentially stating that the purpose of the minor use system is essentially two-fold – firstly to recognise that market failure exists to begin with, and secondly to overcome that market failure.

Berries Australia supports clear development of guidelines based on robust economic modelling to determine which crops and uses can be considered minor use based on the need to effectively address and overcome market failure. Unfortunately, the documents prepared by the APVMA in relation to identifying minor crops (as opposed to minor uses) are neither clear, nor anything that could be considered a guideline in the normal sense of the word. For an organisation that is so dependent on tested and verifiable data for its decision making, it is ironic that the paper appears to have been prepared without any apparent economic modelling.

The consultation process around the development of this document has been characterised by its lack of engagement with those industries most affected by the proposed changes to Schedule 1 which means in real terms the berry industry has had five weeks to review and understand the implications of the potential changes which if enacted will have long lasting effect. In addition, having now had the opportunity to review the original discussion paper put forward in July 2023 and the submissions made, it is notable that despite many of the submissions questioning the approach and the assumptions therein, there has been very little material change to the approach proposed by the APVMA. We also note the feedback from Hort Innovation that APVMA actively engage with any impacted industries, for whatever reason, did not happen.

We consider there is no coherent argument to move blueberries and raspberries from being classified as minor crops to major crops presented in the document and nor do we have any clarity on how the transition will be managed to ensure ongoing access to chemistry. The submissions provided by our members Costa and Driscoll's highlight the very real consequences this arbitrary decision will have on the sector.

Recommendations:

1. That the APVMA immediately pause their intent to implement the proposed "guidelines" with the exception of those commodities who are seeking to move from major to minor as they have demonstrated "market failure".

2. That the APVMA, in consultation with the crop protection industry, research providers and growers, identify the factors that contribute to insufficient access to crop protection products. Berries Australia have already approached Hort Innovation to fund an analysis of how the Australian horticulture industry's access to chemicals compares to the access of our global competitors.

3. That the APVMA develop a robust set of guidelines/decision matrix based on economic modelling in relation to market failure to determine if a crop should be considered a minor crop.

4. That any intent to revoke the minor status of a crop should be accompanied by a five-year transition plan developed in consultation with the affected industry.

The Guidelines

Berries Australia notes that the APVMA's Draft Guidelines for determining minor use (the guidelines), identifies minor use as applying in the following circumstances:

1. Use of a product on a speciality crop or animal grown on a small scale
2. Infrequent use of a product on a major crop for the control of a minor pest or disease
3. Use of a product on a major crop for the control of a minor pest or disease, where the use is restricted to a small proportion of that crop
4. Change in use of a registered product (that would normally require an application for variation) to account for unusual seasonal conditions (for example, changes to the method or rate of application of the product)
5. Use of a product on a newly emerging crop or livestock species

Use of a product on a speciality crop or animal grown on a small scale

The key purpose of a guideline is to provide clear, unambiguous, objective guidance as to the application of set criteria in order to aid decision making. Unfortunately, in relation to determining which crops would be considered for minor use the so-called guidelines achieve none of these things.

Firstly, none of the terms in this statement provide any guidance as to what constitutes crops may be considered for minor use. The term speciality serves no purpose in this context and is entirely subjective. Is a blackberry more speciality than a raspberry or cherry? Is it just animals grown on a small (undefined) scale or also crops? We request that the APVMA return to the original intent of the minor use legislation and define it as a use on a crop or animal where there is insufficient return to the applicant for the cost of registration.

Secondly, in actually determining if a crop could be considered minor in this context, the only criteria seem to be exclusion from a list developed internally by the APVMA. Whilst the use of a list is not problematic per se, it becomes problematic if there are no objective criteria for inclusion on that list that relate to the actual purpose of minor use.

When reviewing the APVMA document the guidelines state that the list was determined based on *"current statistics regarding volume of production, area under cultivation or numbers of trees or animals and the value of crop or animal".* It is frustrating that almost all of the submissions to the previous round of consultations identified that these measures were not an appropriate proxy for determining market failure. In particular, we draw your attention to the submissions provided by Hort Innovation and the Minor Use Foundation. This approach becomes even more problematic when there is no transparency as to how that data was used to come up with the list, or indeed the source of said statistics. The Minor Use Foundation sums up the situation as follows:

> *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 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.*

Estimated farmgate value is a particularly problematic metric as it has no bearing on economic returns to the registrant (i.e. there is no correlation between the perceived farmgate value of a crop

and the economic return for a registrant in registering an active). Ultimately, the economic return will primarily be determined by the volume of an active that will be sold which is not a function of crop value. Even if value was an appropriate metric, the value of horticulture crops is very difficult to establish. Whilst the Hort Stats handbook gives a useful guide, the figures were not designed for this purpose and we can attest that the values assigned to berries are a 'best guess'. Further, on farmgate value it is impossible to properly articulate. For instance, there is enormous differences in the value of oranges for processing (Valencia) and oranges for table fruit (navels) – but they are both oranges.[1]

The additional information provided in Appendix B which supposedly outlines the rationale for inclusion of various crops of the list is problematic and highlights exactly the concerns outlined above. The comparison between the raspberries (proposed to be included on the major crop list) and mushrooms (proposed to be removed from the major crop list) is instructive in highlighting that even when using the meaningless criteria, they are not being applied consistently.[2]

Criteria	**Mushrooms**	**Raspberries**
Value	Not considered but valued at $434 million	$150 million[3]
Number of growers	42	33
Comparative access to crop protection products	Considered niche	Not considered

Based on the only criterion applied to both mushrooms and raspberries, raspberries are clearly the "smaller" crop. To make it even more confusing, the criterion for pineapples relates to tonnage, lemons and raspberries refer to area under production and the rationale for olives seems to relate to value only. There seemed to be no criteria applied at all to the blueberry industry.

We support the contention that mushrooms are inherently challenged with respect to their access to AgVet chemicals but also contend that raspberries are similarly challenged [4]. We highlight the following statement in the Driscolls Australia submission noting that Driscolls is the largest berry grower in the world and as such has a line of sight over chemical access in berries globally:

> *From a global perspective, the relatively small scale of Australian raspberry and blueberry production poses a significant challenge when it comes to securing access to Agvet chemicals. Chemical registrants in international markets often prioritise countries with larger agricultural output, as these provide greater incentives for investment in product registration and market expansion. Australia's comparatively modest production area makes it less*

[1] Pers comm Citrus Australia

[2] Please note, Berries Australia is using this as an illustrative example only and has no intent for mushrooms to be considered a major crop. We need to move away from the arbitrary shuffling of crops from one category to another based on lobbying from industry groups towards a clear defensible set of guidelines that are applied equally and relate to market failure. Clearly the mushroom industry is experiencing market failure hence their need to be considered for minor use.

[3] We are unclear as to where that figure was derived as the industry and Hort Innovation group raspberries and blackberries together under the category of rubus which is valued at a total of $220million.

attractive to chemical manufacturers, potentially leading to fewer available products for local growers.

This above point is key to the whole discussion. The market for AgVet chemicals is a global market therefore market failure has to be examined in this context. For example, the Australian blueberry industry produces approximately 20,000 tonnes per year whilst the Peruvian industry produces ten times that amount (224,000 tonnes) making it a clear winner in terms of return on investment for chemical companies. Whilst we do acknowledge that applying the US metric for minor use as any crop under 300,000 acres of production is not really feasible in the Australian context, it does highlight that we need a nuanced approach that also considers other incentives or mechanisms to ensure that our growers are globally competitive.

The guidelines as they are currently articulated cannot be supported and we make the following recommendations:

That the APVMA immediately pause their intent to implement the proposed "guidelines" with the exception of those commodities who are seeking to move from major to minor as they have demonstrated "market failure".

That the APVMA, in consultation with the crop protection industry, research providers and growers, identify the factors that contribute to insufficient access to crop protection products. Berries Australia have already approached Hort Innovation to fund an analysis of how the Australian horticulture industry's access to chemicals compares to the access of our global competitors.

That the APVMA develop a robust set of guidelines/decision matrix based on economic modelling in relation to market failure to determine if a crop should be considered a minor crop.

Berry specific considerations

As outlined above there seems to be no clearly articulated rationale for the inclusion of blueberries and raspberries on to the major crop list however there are significant implications for the sector if this goes ahead.

Currently berries constitute 30 percent of all minor use permits held by Hort Innovation. This does mean there is significant industry investment in data generation and the cycle of renewals places a bureaucratic burden on Berries Australia and Hort Innovation. Both organisations would be relieved if there was indeed a clear alternative to the current system. That said, we do not think that moving blueberries and raspberries onto the major crop list will solve the problem and will in fact increase the data generation and bureaucratic burden on the sector.

As identified in the submissions from Costa and Driscolls, we are a high value but high-cost commodity with most of those costs not relating to chemical use. The complexity of our cropping systems, the need to manage resistance and our commitment to IPM means that we use a suite of crop protection products, many of which are generic. Focusing on the underlying issue of market failure, we have little confidence that the chemical companies will take on the registration of these products and so the actual outcome of this determination will be that berries will consistently be required to generate more data to access their existing suite of chemicals.

Using the matrix provided, it would seem that all uses for raspberries would be considered minor as the area under production for all of rubus is 962ha[5]. This would seem sufficient justification for raspberries to be considered a minor crop and we request that they be removed from the proposed major crop list.

Blueberries are estimated to have an area under production of 1470 ha which places them in the low end of the medium category, but their value is high, so according to the matrix more information would be required for every single permit application. Again, there is no clarity as to the specific information requirements or what the thresholds are. Considering the permit section within the APVMA is already struggling with workload, it seems counterproductive to require an additional step of demonstrating minor use before the permit process is even initiated.

As identified in the Costa submission, 10 blueberry minor use permits will expire in 2025. The likelihood of any these products being registered by next year is non-existent and considering many of them are generic, it is unlikely they will ever be registered at all. In practical terms this will mean the blueberry industry will have to prove ten times that the use is minor and then the APVMA will have to assess ten times that the request is indeed for minor use, before the permit renewals themselves are even assessed. Considering the APVMA has demonstrated that they are unable to meet their existing obligations in terms of timely permit renewal and that are not meeting their cost recovery targets, adding this extra step seems like an exercise in self-flagellation for the APVMA and a significant risk to chemical access for the blueberry industry.

The subjective application of industry statistics in this process has not given us confidence that the proposed pre-permit minor use assessment process will be efficient or effective. The complete lack of a meaningful transition strategy for the commodities proposed to be moved onto the major crop list demonstrates a very poor understanding of how cropping systems interface with the chemical access system and places our industry at great risk.

The berry industry supports the development of clear, quantitative guidelines around what constitutes minor use based on a firm understanding of the factors contributing to market failure. The existing approach is not fit for purpose, but the proposed new approach is not acceptable and does not adequately consider or address the potential consequences. We would like to work with the APVMA, the crop protection providers and Hort Innovation to identify where market failure exists and look at innovative approaches to overcoming that market failure with minor use permits being just one part of the solution.

In the event of an agreed new system resulting in a re-categorisation, we recommend the following:

That any intent to revoke the minor status of a crop should be accompanied by a five-year transition plan developed in consultation with the affected industry.

Yours faithfully

Rachel Mackenzie
Executive Director Berries Australia

[5] As per Costa submission

Citrus Australia Ltd
94 Lemon Avenue MILDURA VIC 3502
T +61 3 5023 6333
admin@citrusaustralia.com.au
www.citrusaustralia.com.au

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

Dear Director

RE: Draft Guidelines for Determining Minor Use

Citrus Australia welcomes the opportunity to comment on the proposed changes to the Draft Guidelines for Determining Minor Use. Citrus Australia Ltd is the Prescribed Industry Body that represents Australia's commercial citrus growers. Access to modern and effective agrichemicals remains one of the fundamental challenges for the Australian citrus industry. Our agrichemical toolbox is shrinking rapidly with few alternatives entering the market.

The Australian citrus industry produces an estimated 800 000 tonnes annually. This is made up of approximately 500 000 tonnes of oranges, 200 000 tonnes of mandarins, 68 000 tonnes of lemons and minor volumes of limes, grapefruit and pummelo. Approximately one-third of the crop is exported, one third is sold on the Australian domestic market (as fresh table fruit), and one-third is processed into juice. Citrus Australia's 2023-24 tree census indicates that there are 19 000 hectares of oranges planted, 9 000 hectares of mandarins, 1 800 hectares of lemons, 1 000 hectares of limes, and 400 hectares of grapefruit and pummelo. It must be noted however that there is large variation in the age of the trees — with younger plantings not yet bearing fruit and older trees approaching the end of their productive lives. For obvious reasons, younger non-bearing trees require fewer chemical inputs.

From the outset, we would like to express our concern that there has been inadequate consultation by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in developing the draft guidelines. Citrus Australia first became aware of the draft guidelines on 22 August 2024, but to our knowledge, the review commenced close to two years ago. At the time that the draft guidelines were released we were given three weeks to respond. The consultation period was subsequently extended by an additional month, but we feel that this was still largely inadequate.

In global terms, the Australian citrus industry is a small player, producing less than one per cent of global production. As an investment option for AgVet chemicals, Australia represents only a small market for product registrants. In trying to attract investment by the agrichemical companies, we compete with other citrus producing nations for the limited R&D budgets that the companies hold. As a small player, there is limited incentive for the companies to invest their limited R&D budgets in label claims for the Australian industry when compared to the larger citrus producing nations. For these reasons, the Australian horticulture sector relies heavily upon minor use permits to control pests and diseases in certain situations.

Citrus Australia's primary concern relates to the proposed new model and criteria that determine whether a crop is considered 'minor' or 'major' and therefore eligible to be considered for minor use permits. Specifically, we are concerned that one of the criteria for determining minor crops is 'value of the crop'. The APVMA considers that AgVet chemical companies are more likely to invest in label claims for high-vale crops and less likely to invest in

Citrus Australia Ltd
94 Lemon Avenue MILDURA VIC 3502
T +61 3 5023 6333
admin@citrusaustralia.com.au
www.citrusaustralia.com.au

low-value crops. We feel that this assumption lacks any commercial or technical merit. AgVet chemical companies are driven by profit. Profits and propensity to invest are more directly related to the number of hectares planted and the volume of product sold. High-vale crops like berries and cherries would still struggle to attract investment due to the low volume of production.

If the proposed new model is finalised, lemons will transition from a 'minor' crop to a 'major' crop on the basis that lemons experienced a resurgence in plantings from 2014 – 2018. We would like to emphasise that while our 2023 tree census indicates that there are approximately 1 800 hectares of lemons planted nationally, only approximately one-third (600 hectares) are of bearing age. The APVMA asserts in the proposed guidelines that lemons represent a 'lucrative' market for new product registrations. Citrus Australia disagrees with this assertion. Even if a registered product was applied at a cost of $2 000.00 per hectare, this would only equate to annual sales of $1.2 million nationally — but of course this represents a highly-contrived situation and assumes that the product would be applied to every single bearing hectare in Australia. This would simply not be the case. Lemons are grown in every Australian mainland state and the Northern Territory with each region having unique pest and disease challenges — with each region having their own unique agrichemical use patterns. For these reasons, we would hardly view lemons as a lucrative crop for new product registrants as the APVMA asserts.

The APVMA also wrote:

> *"lemons are a representative crop for the citrus crop group, so registration in lemons can provide for extrapolation to other crops within the group, making registration more economical".*

We do not agree with this statement. Two-thirds of the lemons cultivated in Australia are grown in the tropics and the sub-tropical regions of Queensland, while the temperate areas of the southern states and Western Australia are dominated by oranges and mandarins. The pests and disease threats in the different regions are substantially different. As opposed to other crops that flower only in spring, Queensland lemons experience multiple flowerings throughout the year and therefore multiple harvest periods. This makes lemons a challenging crop to protect with agrichemicals due to restrictions around maximum residue limits, withholding periods and orchard re-entry periods. Moreover, the multiple flowering pattern prohibits the use of certain actives (namely neonicotinoids) due to their impacts on bees and other pollinators during flowering. Case in point: citrus gall wasp is one of the most significant pests of citrus in Australia. The neonicotinoids are the only product registered to control this pest effectively but cannot be used on Queensland lemons for the reasons stated. Given these differences, considering lemons a representative crop for the entire citrus category is not a sound proposition.

Citrus Australia considers the draft guidelines to be premature. We respectfully request that the APVMA undertakes further consultation with us and take our comments into consideration before finalising the guidelines.

Yours sincerely

[redacted]

10 October 2024

Australian Pesticides and Veterinary Medicines Authority (APVMA)
GPO Box 3262
Sydney NSW 2011

Email: enquiries@apvma.gov.au

To whom it may concern,

Re: Submission in response to APVMA call for public comment on the review of the guidelines for determining a minor use permit

Costa Group welcomes the opportunity to make this submission as a grower of both Blueberries and Rubus (raspberries and blackberries).

Costa grows blueberries in New South Wales, Queensland, Tasmania and Victora, and raspberries and blackberries in New South Wales and Tasmania. Much of this crop is grown under protective poly tunnels, with more than 50% blueberries grown in substrate (out of the soil).

APVMAs role and potential for inconsistencies in meeting its various stated aims and desired outcomes

In framing the arguments that this submission makes in favour of retaining the classification of the Blueberry and Rubus crops as 'minor', as opposed to categorizing them as 'major', we believe it is both helpful and instructive to note comments made by the then Agriculture Minister, David Littleproud when introducing the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019,* and the preamble to the Agricultural and Veterinary Chemicals Act (CW) 1994.

Noting Minister Littleproud's comments first:

'Australians need access to safe and effective agricultural chemicals and veterinary medicines.'

'Agvet chemicals, as these products are commonly known, have brought long-term benefits to Australian agriculture by supporting increased productivity, better quality produce and more competitive industries.'

'The APVMA needs to be both efficient and effective in its regulation of agvet chemicals'[1]

With reference to the preamble to the Act and which likely informed the Minister's comments above, of specific interest to note are paragraphs a) and c), which state as follows:

[1] Hansard – House of Representatives 18 September 2019

(a) that the protection of the health and safety of human beings, animals and the environment is essential to the well-being of society and can be enhanced by putting in place a system to regulate agricultural chemical products and veterinary chemical products; and

(c) that the furthering of trade and commerce between Australia and places outside Australia, and the present and future economic viability and competitiveness of primary industry and of a domestic industry for manufacturing and formulating such products, are essential for the well-being of the economy and require a system for regulating such products that is cost-effective, efficient, predictable, adaptive and responsive;

The then Minister's comments and the preamble to the Act, highlight what may be seen as competing priorities if not given due consideration when determining whether a crop is minor or major.

These priorities exist between the stated aim of using safe and effective chemicals and protecting the health and safety of human beings et al. (akin to the precautionary principle), which every Australian quite reasonably expects a regulator such as APVMA to guarantee and is not in dispute here, versus the ability to access such chemicals

This access must be at a cost that ensures Australian farmers can be productive and competitive, grow and supply products which are indeed both safe and healthy, but also affordable for consumers, supplying not only the domestic market, but also export markets, ie. *furthering of trade and commerce between Australia and places outside Australia.*

It is the impact and capacity for the APVMA and indeed the parliament to satisfy paragraph c) of the preamble that is the cause for concern, should Blueberries and Rubus be recategorized as major crops.

Specifically, it highlights why access to minor use chemicals especially in the absence of such chemicals being manufactured in Australia (at least to Costa's knowledge) and in so called commercial volumes, is so important for many crops, including the Blueberry and Rubus crops.

Minor use permits are also such an important tool to level the playing field for Australian agriculture, which due to a lack of scale (compared to the rest of the globe) and the elimination of tariff protections by successive governments, effectively rendered Australia as a location in which it has long been uneconomic to manufacture and sell certain agvet chemicals.

Our primary concern is that by categorizing the Blueberry and Rubus crops as major, this will add additional and costly barriers to accessing relevant agvet chemicals, including a number that have existing minor use permits attached to them, and are which due to expire in the near future.

At its worst, it will result in a situation where these crops will not be able to access the chemicals they need in order to grow produce that is pest free, safe, of a high quality, and is affordable for as many consumers as possible. There is also the potential for there to be an adverse impact on our nation's food security, and our ability to compete in export markets.

Criteria used to determine a major crop

Based on empirical data, we question the criteria used by APVMA based on value and acreage, to determine that the Blueberry and Rubus crops should be no longer categorized as minor. In particular, and in the absence of any further details as to how the definitions of low, medium and

high were determined, we make the following comments in response to what we contend are the flawed application of value and acreage.

- **Value**

Blueberries and Rubus are both intensive plant crops which require significant cost inputs including:

Procurement and establishment of land –purchase/rent, surveying, earthworks, installation of supporting infrastructure (ie. dams, protective tunnels) and any necessary planning approvals.

Planting and maintenance of the crop - in the case of raspberries, replanting can occur every season. Maintenance of the crop includes the use of inputs such as labour, water, nutrients and pesticides/insecticides.

Harvesting – all by hand, with raspberries packed in the field.

Processing and transport – occurs in a controlled environment and must be shipped in a timely manner, which is reflected in the highly perishable nature of the crops.

These costs, in which the labour component commonly makes up >50% of total production costs (versus significantly less for broadacre crops), need to be properly weighted against the apparent value of the crops and in particular economic return after costs, in order to properly consider and understand the actual value and return on capital (both capital expenditure and ongoing operating expenditure).

As with many other sectors of the Australian economy, Blueberry and Rubus growers have also had to contend with significant cost input inflation pressures over the last three to four years, much of which has occurred due to factors beyond any one grower's control. This has included significant high double digit increases in the cost of fertiliser/chemicals, packaging, energy and transport.

There has been no corresponding, or equivalent increase in pricing for Blueberries and Rubus, that would support any evidence or suggestion of an increase in value, net of actual costs.

Viewed in this light, it is clear that the Blueberry and Rubus crops are still minor crops. At the very least, we urge APVMA to provide more detail on the basis of how the value thresholds were determined before any final decision is made.

- **Hectares/Acreage**

We note the HIAL Hort Statistics Handbook 2022/23, estimates a total Rubus production area of 962 hectares (2,377 acres - 75% raspberries, 25% blackberries and 1% other), with nearly 30% of this area located in Tasmania.[2] Based on any reasonable measurement, including the proposed guidelines, this should be considered a minor industry.

Blueberry production, which due to the availability of different varieties occurs year-round, is estimated to occur across a production area of 1,470 hectares (3,632 acres). HIAL also notes that Australia has traditionally been a net importer of fresh blueberries, typically importing 1,000-1,700

[2]https://www.horticulture.com.au/contentassets/a36fdfa2427d4ad284c426663b06f15c/hort-stats-fruit-22-23.pdf

tonnes per year, with the majority of this volume coming from New Zealand. For the year ending June 2023, Australia imported 788 tonnes.[3]

The status of Australia as a net importer of blueberries primarily reflects the absence of Australian grown blueberries having access to the two biggest and most lucrative Asian export markets, namely China and Japan. The absence of such markets suggests it is unreasonable to categorise Blueberries as a major crop, with the proposed guidelines categorising it as a medium crop. Raspberries by their highly perishable nature are considered not suitable for export and would not generate sufficient economic value versus the cost incurred.

We also refer again to the preamble of the Act at paragraph c) *'…the furthering of trade and commerce between Australia and places outside Australia'*, and express concern that if and when market access is achieved for Australian grown blueberries to these markets, the industry will not be in a position to benefit due to an inability to access chemicals in a cost effective and timely way.

We also note the way in which other countries/jurisdictions determine minor use crops by application of a clear threshold metric based on crop area. In the United States for example, minor use crops are categorised as having fewer than *300,000 acres* (121,405 hectares) in production. The USEPA notes small acreage may provide insufficient economic incentive for pesticide companies (i.e., registrants) to keep their products registered for use on these crops, or to register new minor use pesticides… without these comparatively small-scale but vital pesticide uses, many of the fruits, vegetables and ornamentals enjoyed in the U.S. and valued at billions of dollars *could not be grown* successfully.[4]

APVMA should consider developing and applying such a definitive metric in order to make clear the distinction between a minor and major crop.

Creating additional cost and barriers to accessing chemicals

The proposed new guidelines are intended to assist applicants to access chemical use through a minor use permit if they meet criteria in:

Schedule 1 – which defines those crops which are major in Australia, and therefore crops not listed are considered minor and they can possibly apply for a minor use permit.

Schedule 2 – which defines a scenario where, regardless of crop classification, the use of the chemical is limited either in space or time (e.g. temporary outbreak during a particular season; or specific pest outbreak limited to a region or State of Australia).

Schedule 3 - which defines that regardless of Schedule 1 and 2, use of a chemical is granted where no sufficient economic return is generated by registering the product for a specific use (crop).

We note and fully support the requirement that a product registrant or permit applicant (as the case requires) must provide appropriate supporting information to the APVMA to demonstrate that the proposed chemical product and its use(s) will be safe and effective**.** This requires the provision of data which include among other things, trialling for efficacy (ie. in the case of a new target pest), safety and residue.

[3] Ibid

[4] https://www.epa.gov/pesticide-registration/minor-uses-and-grower-resources

We are however concerned that the loss of access to minor use or approved 'off label' uses, including generic active ingredients will limit access to chemicals, by adding to the complexity of obtaining approval and the end cost.

If categorised as major, the only possible scenario where the Blueberry and Rubus crops could apply for a minor use permit will be for treatment of a pest that is specific to a geographic area (e.g. chilli thrips in Western Australia) or any situation where it can be demonstrated that the use is limited in time or space, to justify it being not worthwhile to register.

In the absence of being able to access chemicals through a minor use permit, accessing and using so called 'on label' chemicals (and depending on the requirements prescribed by APVMA), will likely require the generation of more data to support the registration. For example, the current APVMA guidance on residue trial numbers indicates 8-12 trials for major crops, 4-6 for minor-major crops and two trials for minor crops. This highlights the increase in cost associated with a change from minor to major, with all of this data needing to come from an approved GLP entity at a cost to the registrant, who will have little incentive to do so given the size, or lack thereof, the market for that chemical.

Expiration of minor use permits for generic active ingredients

We are also concerned about the pending expiration of minor use permits for a number of generic active chemical ingredients.

Blueberries currently have access to 26 active minor use permits, 10 of which are due to expire in 2025. Rubus has access to 32 active permits, 12 of which will expire in 2025.

This includes access to the use of up to 15 active chemical ingredients, such as mancozeb, captan, and copper hydroxide, all of which are currently out of patent and sold under different brand names, and by different manufacturers or distributors.

There is no guarantee that these would continue to be available beyond expiration of minor use permits and therefore use of these would be lost. This is in part because none of the conditions set by the proposed minor use permit guidelines will allow such renewal, compounded by the fact that it would be unlikely they would be moved to on label by a manufacturer, as there would be none prepared to fund this, given the level of information that would need to be generated, and due to the relatively small market that exists.

The industry could seek to provide additional data to support a move to on label, however given the number of residue trials as noted above, this would require a number of years, and potentially tens of thousands of dollars in expenditure (per active ingredient), depending on specific information that may be requested by APVMA.

We believe this will continue to be the case with respect to chemicals used by Blueberries and Rubus crops and we are concerned that access will be lost to a number of active ingredients as a consequence of being categorised as major crops.

In order to realistically address such scenarios, Blueberries and Rubus will need a grace or phase out period of at least three to five years in order to properly address and satisfy the time and cost required to address the knowledge and information gaps, in order to successfully move those chemicals to on label. Even then, this is not a guaranteed outcome, potentially resulting in

suboptimal outcomes, especially if resources are not made available by APVMA or elsewhere in government to help fund such processes.

Impact on effectiveness of integrated pest management (IPM)

Effectively managing and mitigating the impact of pest and disease on a crop often requires a complex strategy, involving not only the use of multiple chemicals, but also IPM compatibility when such pest management tools are used. This is consistent with the desire of Costa and many others in the industry to protect biodiversity, minimise plant pest resistance, and seek to reduce, where practical, their chemical use in favour of increased IPM use.

Unfortunately, this will be more difficult, because as challenging as it may be now, accessing chemicals in the future for use mostly through on label, will only magnify the current existing gaps in pest and disease management and the capacity to access product compatible to greater IPM use.

Conclusion

In conclusion, we note and agree with AUSVEG's view that the fact so many crops, major and minor, currently lack sufficient registered options for endemic pest, disease and weed problems should act as a significant indicator to alert the APVMA to the fact that for many uses registrants have had little or no interest.

The reason for off-label use is unambiguous in our view, namely it is intended to enable the use of agricultural and veterinary chemicals in situations where extending label uses may be uneconomical for chemical companies, for example, minor crops, of which Blueberries and Rubus both are, including for the reasons stated in this submission.

As the preamble to the Act notes, this requires a system for regulating such products that is cost-effective, efficient, predictable, adaptive and responsive. Any new guidelines must reflect this, while also protecting the health and safety of human beings, animals and the environment.

As noted, this can create competing priorities, which APVMA must seek to exhaustively consider and address, so as to avoid sub optimal outcomes with respect to removing the capacity to access minor use permits.

Yours sincerely,

Robert King

General Manager – Berry Category
Costagroup

CropLife Australia

October 2024

Draft Guidelines for Determining Minor Use

Public Consultation

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 $31 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 on the Public Consultation to the *Draft Guidelines for Determining Minor Use*. Considering the dynamic nature of the agricultural landscape, it is crucial to ensure the system is adaptive to 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] Deloitte Access Economics, 'Economic Contribution of Crop Protection Products in Australia', August 2023, https://www.croplife.org.au/resources/reports/economic-contribution-of-crop-protection-products-in-australia/

[2] Deloitte (2019) Agvet Chemicals – Market Drivers and Barriers

2. GUIDE FOR DETERMINING A MINOR USE

In comments provided to the June 2023 Discussion Paper, CropLife acknowledged the need for revisiting the existing guidelines, which were initially formulated in the early 2000s. However, we do agree with the Veterinary Manufacturers and Distributors Association Ltd, that the elapsed time does not necessarily equal the need for dramatic changes. We also acknowledge that the agricultural landscape has undergone significant changes since the most recent review. As several peak commodity groups have argued, crops that were once considered major, may now have a diminished market share, and previously minor crops may have experienced substantial growth in popularity or value.

While several of the crops proposed for removal from the current *Schedule 1 – Minor crop, animal or non-crop situation* have been removed due to substantial contraction in planted acreage, the inclusion of several others seem to be irrespective of these figures, focusing solely instead on the production value of the crop. It is therefore critical that any updated guidance does not seek to impose inflexible adjudication between crops as minor or major based on production or export values; rather the intent of the Minor Use Guidelines must be to pursue unmet crop protection needs that producers identify as priorities.

For context, the United States of America definition automatically includes all crops under 300,000ac. This number would clearly capture the majority of the horticultural crops grown in Australia.

Importantly, CropLife notes that the inclusion of a crop in *Section 1 – Major crops, animals and situations* does not automatically preclude there being a minor use within that crop, and further note that this is addressed in Section 2.

CropLife also posits that while exemption from the list of major situations is intended to reduce regulatory burden for applicants, the unwarranted addition of a crop to Section One radically increases it. The rationale provided for the proposed inclusion of several new crops to the list, is a result of their status as representative crops for their respective Crop Group. As a representative crop, registration in said crop can provide for extrapolation to other crops within the group, making registration more economical. This has two flaws. Firstly, if this allowance is not being capitalised upon, this should satisfy the APVMA that reasonable grounds for a permit exist, as there are not suitable and effective registered chemical products or approved active constituents with the same purpose. Secondly, Crop grouping 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.

The Permits guideline made pursuant to subsection 6A (1) provide information on what may be considered minor in terms of economic return and reasonable grounds for issuing permits. As such, we support and concur with the Minor Use Foundation (MUF) recommendation for a simplified approach and overarching guidance.

> *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*

This same guideline also states '*there will not be reasonable grounds if there are suitable and effective registered chemical products or approved active constituents with the same purpose*' which provides an adequate, necessary backstop to guide the APVMA in determining whether 'reasonable grounds' exist for the issuing of the permit (section 112 of the Agvet Code).

We also agree with the MUF that this could be expanded, through modification (as underlined) of an existing circumstance to

> *"Where commodities are <u>either</u>*
>
> *(i) required to be treated with the product or constituent or*
>
> *(ii) <u>lack sufficient registered products</u> to meet particular market access requirements".*

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 matrix proposed by the APVMA regarding the delineation between certain crops under *Section 2 (Limited use within a major crop, animal or non-crop situation)* is therefore appropriate. While CropLife was supportive of taking the value of the crop (or animal) into consideration for the development of Minor Use guidelines, changes in popularity and value should not form the dominant criteria for inclusion in the proposed *Section 1 – Major crops, animals and situations*; this must be weighed against the planted area of a crop. High value, small acreage crops paradoxically have the effect of reducing investment in crop protection options. This is addressed in Section 2, which does provide a more transparent and methodical thought process to the determination of a minor use.

However, the proposed additions to *Section 3 - Demonstrating insufficient economic return,* has increased the complexity, cost and burden associated with the determination of a minor use. Further, the costs of a PAA (Tier two) are proposed to increase by as much as 326 per cent in the proposed Cost Recovery Implementation Statement (CRIS) for 1 July 2025 to 30 June 2026. The rebates, however, are increasing as little as 180 per cent and are contingent upon an application being lodged. This increase will further disincentivise applicants from utilising this pathway, which will again result in farmers being denied access to chemical products available to their overseas competitors.

The current guidance laid out for Schedule 3 is already clear, and appropriate. 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. We reiterate that 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.

3. NEXT STEPS

Section 1A (1) of the Agvet Code recognises that the present and future economic viability and competitiveness of primary industry, which relies on access to chemical products and their constituents, are essential for the well-being of the economy and require a system for regulating chemical products and their constituents that is cost effective, efficient, predictable, adaptive and responsive.

While CropLife is pleased that the APVMA is committed to modernising and improving the minor uses guidelines, it must also be recognised that addressing the 'minor use problem' cannot be accomplished by increasing the complexity and burden of determining a minor use.

As CropLife put forward in comments to the Discussion paper, 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. We reiterate that this should be core work of the Agvet Policy branch of the Department of Agriculture, Fisheries, and Forestry,

Over several years, CropLife has posited means and mechanisms to address the minor use problem in Australia. These, however, are policy discussions which are distinct from this consultation on establishing determination guidelines. We maintain this commitment to working collaboratively with the Commonwealth, States and Territories, DAFF, the APVMA, and growers to implement effective and fit for purpose solutions to this problem, rather than stop-gap and finite funding to generate data to support permit applications.

At minimum, 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. 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 over 1070 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

4. CONCLUSION

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 in other countries to invest in minor crop pesticide registrations 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.

CropLife suggests implementing a minimum five-year phase-out period, whereby any additions to the Section 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. Care must be taken when adding or removing crops from Section 1, given the commercial realities and resource constraints associated with generating the necessary data for minor use crops or pests.

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.

Driscoll's Australia
Level 5, 818 Bourke Street
Docklands VIC 3008

10 October 2024

Australian Pesticides and Veterinary Medicines Authority (APVMA)
GPO Box 3262
Sydney NSW 2011
By email only: enquiries@apvma.gov.au

To whom it may concern

Re: Submission in response to APVMA call for public comment on the review of the guidelines for determining a minor use permit

Driscoll's Australia welcomes the opportunity to make this submission as the leading marketer of fresh berries in Australia. Driscoll's markets fresh berries including blackberries, blueberries, raspberries, and strawberries, which are grown by independent growers and sold by Driscoll's to major retailers and independent stores throughout Australia.

Driscoll's and our growers fully support the regulation of chemicals to ensure their safe and effective use in agriculture and recognises the need to update guidelines and policies in line with changing market conditions. The current Agricultural and Veterinary Chemicals Code act 1994 states that 'the present and future economic viability and competitiveness of primary industries, relies on access to chemical products and their constituents.'[i] The legislation also calls for a regulatory system that is 'cost effective, efficient, predictable, adaptive and responsive' while balancing regulatory effort with the burdens placed on holders of approvals, registrations, permits, and licenses, as well as the domestic industry involved in manufacturing and formulating these products.

This framework underlines the importance of Minor Use Permits for crops such as raspberries and blueberries, where access to specific chemicals is crucial for crop protection. Continued access to these chemicals under Minor Use Permits is essential to the ongoing economic viability of our berry growers. Reclassifying raspberries and blueberries as major crops would impose significant additional costs and resource burdens on berry growers and suppliers, making it more challenging to access vital Agvet chemicals.

Criteria used to determine a major crop – Hectares

According to Hort Innovations Hort Statistics Handbook 2022/23[ii] total rubus production, which includes raspberries (75%), blackberries (25%) and other (1%), covers 962 hectares (Ha). Based on any reasonable assessment, including the proposed guidelines, this production would be considered a minor crop. The classification of Rubus as a minor crop reflects both its limited production area and the specific chemical needs of growers, which are not typically addressed by broad-spectrum chemical products registered for major crops.

In contrast, blueberry production covers a slightly larger area, estimated at 1,470 hectares. However, Australia remains a net importer of fresh blueberries, importing between 1,000 and 1,700 tonnes annually, primarily from New Zealand, as highlighted in the Hort Statistics Handbook[iii]. Given this context, it is unreasonable to categorise blueberries as a major crop.

From a global perspective, the relatively small scale of Australian raspberry and blueberry production poses a significant challenge when it comes to securing access to Agvet chemicals. Chemical registrants in international markets often prioritise countries with larger agricultural output, as these provide greater incentives for investment in product registration and market expansion. Australia's comparatively modest production area makes it less attractive to chemical manufacturers, potentially leading to fewer available products for local growers. This reinforces the need for a regulatory framework that supports access to necessary chemicals through Minor Use Permits, especially for crops like raspberries and blueberries, which do not hold the same market share globally as major crops.

Criteria used to determine a major crop – Value, export quantities, consumption

Driscoll's raspberries and blueberries are intensively grown, usually under protected cropping systems, such as poly tunnels. Berries are high value due to being a highly perishable crop harvested by hand usually requiring significant investment in protected cropping infrastructure such as irrigation systems and polytunnels. Crop value does not reflect chemical usage or need and is not a useful criterion for determining major or minor crop status.

Raspberries and blueberries are a highly perishable products which require growers to harvest at frequent intervals. To reduce pest and disease resistance, a suite of products is required which all have very low minimum harvest intervals to optimise fruit maturity and reduce pest and disease resistance. Legal access to appropriate pesticides and fungicides is an integral part of Integrated pest and disease management. Categorisation of crops as major or minor should be limited to factors which evaluate the availability of management options for pests and diseases, severity of pest and disease impacts, and the economic viability of investing in registration in Australia, rather than factors such as crop value, export quantities or dietary consumption.

Minor permits with generic active ingredients

Chemicals containing generic active ingredients have little financial incentive for manufacturers to pursue on-label registration. Categorising blueberries and raspberries as major crops will increase the burden on berry growers to develop business cases to justify a use as minor when applying for minor use permits.

Currently, Driscoll's growers have access to 32 minor use permits for raspberries, with 12 due to expire in 2025, and 26 permits for blueberries, with 10 expiring in 2025. Driscoll's is particularly concerned about the pending expiration of these minor use permits, which includes several generic active chemical ingredients.

Conclusion

In conclusion, Australia's small market size is a disincentive for registrants to invest in permit to label registration and changes to the current crop status of blueberries and raspberries will increase the administration burden on our business to gain access to regulated chemicals.

The Schedule 1 criteria to categorise blueberries and raspberries as a major crop appears flawed as it does not adequately recognise appropriate uses for specific chemicals, or the unmet crop protection needs of our growers. Industry statistics such as dietary consumption, export volumes and crop value are not relevant to assessing reasonable grounds for crop categorisation or minor use justification. The proposed changes may result in a loss of access to chemicals and damaging economic impacts on our growers and industry.

Failure to address the specific needs of berry crops within the regulatory system could undermine the competitiveness of the Australian berry industry. Driscoll's recommends raspberries and blueberries remain categorised as minor crops to ensure that the regulatory burden remains manageable for growers and industry, while also facilitating access to the specialised chemicals required for crop protection and productivity. In a highly competitive global marketplace, it is essential that Australia's regulatory framework remains adaptive and responsive to the unique needs of smaller-scale crops to safeguard the industry's sustainability and future growth.

---

[i] https://www6.austlii.edu.au/cgi-bin/viewdoc/au/legis/cth/consol_act/aavcca1994382/sch1.html

[ii] https://www.horticulture.com.au/contentassets/a36fdfa2427d4ad284c426663b06f15c/hort-stats-fruit-22-23.pdf

[iii] https://www.horticulture.com.au/contentassets/a36fdfa2427d4ad284c426663b06f15c/hort-stats-fruit-22-23.pdf

Director, Permits and Minor Use
APVMA
GPO Box 3262,
Sydney NSW 2001, Australia

11 October 2024

Draft Guidelines for Determining Minor Use.

GRDC wishes to provide the following comments regarding the recent public consultation document of the "Draft Guidelines for Determining Minor Use".

Firstly, the GRDC would like to reiterate elements of its 2023 submission. Namely, it would be helpful if the APVMA could provide background information on how the current criteria for determining minor use were chosen, were applied, and the basis for the proposed changes.

The current Guideline indicates that the criteria for determining whether a particular use can be defined as minor are "based on the volume of commodity production, area under cultivation, dietary consumption, value of the crop and export quantities".

It is assumed that the inclusion of dietary consumption and trade related to managing regulatory risks.

However, as the Table 2 matrix, in the current Draft Guideline, only considers acreage and crop value, it appears these are now the primary criteria being considered.

Is this correct?

If that is the case, it would be helpful to understand how the thresholds for low, medium and high were arrived at, given they drive a crops classification and the type of information to be provided as outlined under the draft Guideline.

Secondly, as acknowledged in the APVMA's 2023 consultation document "*the issue of 'sufficient economic return' can be difficult to determine for both the applicant and the regulator*". GRDC is concerned that without an understanding of the basis for the draft Guideline thresholds there is a risk proposed minor uses could, unnecessarily, be guided to Schedule 3, i.e., having to demonstrate insufficient economic return.

The problem, from a user industry perspective, is that it would be unrealistic to expect users to be in a position to provide the type of information indicated, e.g., potential returns on investment, expected sales volumes and sales margins.

Further GRDC believes the APVMA needs to provide more detailed guidance around what can constitute reasonable grounds, in the context of proposed uses being considered minor and the type of information required. From that standpoint it is suggested that the APVMA give greater consideration to developing additional criteria to better characterise issues around the scale and nature of industry needs rather than relying on thresholds of a crop's dollar value or acreage.

By way of illustration the GRDC notes the draft Guideline provides five examples on page 9 which essentially replicate information that is currently required suggesting this element has not been progressed.

Engaging more deeply with user industries would provide the APVMA with an opportunity to reassess the current framework and develop more comprehensive criteria to not only assist the APVMA but also users reliant on chemical access through minor use permits.

In summary the GRDC believes greater transparency is needed around how the criteria for determining minor use have been developed. In addition, it is suggested the APVMA should seek greater engagement with user industry stakeholders to ensure the minor use system is continues to play an important role in furthering access to safe and effective farm chemicals in Australian agricultural production.

Regards

Gordon Cumming
Manager Chemical Regulation
[redacted]
W: www.grdc.com.au
E: gordon.cumming@grdc.com.au

Hort Innovation

20 September 2024

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

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 $16 billion 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 stands as one of the most diverse sectors within agriculture, encompassing a vast array of crops and crop types tailored to meet the varied needs of the Australian community. Ensuring that growers have access to essential tools to enhance both productivity and profitability is a critical focus for Hort Innovation. Among these tools, Agvet chemicals play a pivotal role, though access can sometimes be challenging, particularly for growers of minor crops. Recognising this, Hort Innovation actively supports initiatives aimed at updating the guidelines for determining minor use, thereby addressing this significant issue.

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 and proposed criteria on which the existing minor use guideline is based and will be based. These criteria do not adequately address the determination of whether a proposed use is minor.

What is a minor use? Page 3 Draft guidelines for determining minor use

The term 'minor use' encompasses various options, yet these options are often vague and largely subjective. Terms such as specialty crop, small scale, infrequent use, control of a minor pest or disease, use registered to a small proportion of that crop, unusual seasonal conditions, and use of a product on a newly emerging crop are not clearly defined. This lack of clarity can lead to misunderstandings and misinterpretations when minor use permit applications are prepared by the permit holder and assessed by the APVMA. Hort Innovation recommends that the APVMA clearly define these terms and include them in a glossary on the APVMA website.

Section 1 – Major crops, animals and situations Pages 4-6 Draft guidelines for determining minor use

The guideline states that the classification of major/minor in Schedule 1 is based on three elements: volume of production, area under cultivation or numbers of trees or animals and the value of crop or animal. 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:

Horticulture Innovation Australia Limited
ACN 602 100 149
Level 7, 141 Walker Street NORTH SYDNEY NSW 2060 AUSTRALIA
Telephone 02 8295 2300
horticulture.com.au

1. 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. For example, in the proposed changes to the list of major crops, animals, and situations, lemon is now considered a major crop due to an increase in area planted over a six-year period and because it is a representative crop for the citrus crop group.

Hort Innovation believes this classification to be flawed for several reasons:

- **Lack of Specific Assessment**: Lemon is not being assessed per se and under other criteria whether it is a minor or major crop but purely because it is a representative crop of the citrus crop group. This classification provides extrapolation to other crops within the group, making registration more economically viable, but does not accurately reflect the status of lemon itself.

- **Discrepancies in Production Volume**: Another example where this classification is flawed is making celery a major crop based on similar production value and quantity as asparagus, yet production volume is vastly different for the two crops. For the year ending June 2023, celery had a production volume of 56,472 tonnes, while asparagus had a production volume of 5,296 tonnes for the same period. The proposed minor use classification regards them both as major crops based solely on production value and quantity, even though their production volumes differ by ten times.

- **Forced Classification**: Because celery is a representative crop for Group 017 Stalk and Stem Vegetables, it is, like other similar crops, 'forced' into the major crop group. The same argument applies to the addition of cucumber and zucchini to Group 011 Fruiting Vegetables – Cucurbits. In this case, the comparison of cucumber and zucchini is made with capsicum and asparagus – not with melons and pumpkins, the other two major crops in this group.

Hort Innovation does not support the addition of cucumber and zucchini to this group for the following reasons:

- **Inconsistent Comparisons**: Cucumber and zucchini do not compare in production area and production volumes to melons and pumpkins. The addition of cucumber and zucchini to this group because they are representative crops is also unfair.

In summary, while area under cultivation and production volumes are useful metrics, they should not be the sole determinants for classifying crops as major or minor. A more nuanced approach that considers specific crop characteristics and market dynamics is necessary to ensure fair and accurate classifications.

Section 2– Limited use within a major crop, animal or non-crop situation Pages 7-8 Draft guidelines for determining minor use

It is commendable that the APVMA has created a matrix to classify uses based on the area, number of plants or animals to be treated and the value of the commodity and that will be used for minor use determination. There is however a concern that the 'low', 'medium' and 'high' classifications of the areas or number of plants to be treated per annum have not been accurately determined. How did the APVMA decide on these values? Will the APVMA amend these areas or number of plants if these are found to be inaccurate? If so, how often will these amendments take place?

Hort Innovation still proposes that the APVMA consider emulating the approaches followed internationally and consult with industry groups in the creation of a matrix to prioritise 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.

Situations where we will ask for more information: Pages 7-8 Draft guidelines for determining minor use

Hort Innovation raises concerns about the extensive information required for minor use permit renewals or new applications. The criteria are often excessive and sometimes unattainable. For instance, obtaining a declaration from product registrants that a use would not be commercially viable to register is particularly challenging. As a result, fewer registrants are willing to include certain use patterns on their product labels, and many find it burdensome to provide such declarations.

Hort Innovation argues that not all three conditions—scales of use under the permit, evidence of discussions with product holders about registration, and the generation of further data—should be mandatory for each permit renewal. The requirement to generate additional data might be viewed as an unfair tactic by the APVMA to collect information that could later facilitate the registration of use patterns in pesticide or herbicide products. Hort Innovation believes that any extra data requirements should be strictly for permit updates and not for registered products.

Hort Innovation welcomes this opportunity to provide feedback on the "Draft Guidelines for Determining Minor Use". If we can provide any further information, please do not hesitate to contact me. Hort Innovation is eager to continue our collaborative efforts in refining these guidelines for determining minor use. We value the input and expertise of our stakeholders and look forward to further consultations to ensure these guidelines meet the needs of the industry effectively.

Yours sincerely

Claud Warren
Regulatory Affairs & Crop Protection Manager
Horticulture Innovation Australia
Level 7, 141 Walker Street
NORTH SYDNEY, NSW 2060
[redacted]

11 October 2024

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

Email: enquiries@apvma.gov.au

To whom it may concern,

REVIEW OF GUIDELINES FOR DETERMINING MINOR USE - RE-CATEGORISATION OF SALMONIDS TO MINOR SPECIES

Access to safe and effective veterinary medicines is critical to the sustainable future of the salmonid industry. Veterinary medicine use in salmonids is very different to that of terrestrial animals, and indeed very different between salmonid species. Unique health, welfare, and biosecurity challenges, including diseases specific to Tasmania, require targeted management strategies and specific veterinary chemical uses as deemed appropriate by the supervising veterinarian.

Currently, all veterinary products in the salmon industry are used as minor use applications or under veterinary prescription due to sporadic need, limited use, or use of products that are regularly refined and updated, making registrations unviable.

Atlantic salmon *(Salmo salar)* are a valuable commodity, but they are only grown in a small part of Tasmania, and across just three producers. They are also farmed on a very small footprint of just 1km² of Tasmanian marine waters. This is in comparison to the >63,000 farming businesses that are producing beef from 43% of the country's landmass in 2023 (wwf.org.au). In addition, the production volumes of Atlantic salmon are much less than those of other Major food species in Australia. According to the Australian Bureau of Statistics and Meat & Livestock Australia, in 2023, production of Atlantic salmon was just 4% of that of the beef industry and 6% of the poultry industry. We are therefore a **minor species** on this scale, and most importantly, our use of veterinary medicines is all **minor use.**

Our industry is particularly vulnerable to health and biosecurity risks, and we already have an extremely limited toolkit of veterinary products available, including those under Minor Use Permit (MUP). This is very different to the other listed Major species where there are numerous registered veterinary products available. Further restricting the options for salmon aquaculture, by making it more difficult and time consuming to acquire MUPs, would be very detrimental to our industry.

This is particularly important for our vaccine products. All vaccines are developed locally in Tasmania through collaborative government and industry R&D. These products are therefore bespoke, and subject to continual evolution and improvement as new pathogens emerge and are incorporated into multivalent formulations. Formulations also undergo regular changes to accommodate strain variability, and other recipe improvements such as dose, adjuvant volumes and adjuvant types. Requiring these vaccines to be registered would be counterproductive because it would:

- Result in a system that was not fit for purpose for the salmon industry, because vaccines would be outdated before the 3-5 year registration process was complete. This would waste resources and leave the industry without access to the latest and most effective vaccines
- Deter our single manufacturer from progressing registrations because the products are likely to be superseded before the registration process is complete
- Deter continuous improvement of vaccine formulations due to the costs to register resulting products
- Deter R&D efforts to rapidly incorporate new antigens into new/existing vaccines, thereby having negative flow-on effects to the health, welfare and biosecurity of salmon in Tasmania
- Increase the time delay between identification of a new effective vaccine and delivery to susceptible fish, leading to increased mortality and production losses on-farm
- Create significant extra costs in the production of boutique vaccine products which are critical for protection against emerging aquatic animal diseases.

It is important to note that a range of different salmonid species can be farmed, so it is not appropriate to aggregate these into one group as 'Salmonids'. Categorising Atlantic salmon as a major species does not achieve any practical or beneficial outcomes for our industry, manufacturers or suppliers. It instead creates a burden of administrative work and cost for those suppliers that service the aquaculture industry, because every veterinary product will need to be retained under a Minor Use Permit (MUP) or veterinary prescription because of the insufficient economic returns to register.

Despite the guidelines for determining minor use indicating that MUPs are still accessible in some situations for Major species, there is real concern that the need to repeatedly justify and furnish all necessary information to satisfy Section 3 of the guidelines every time a MUP or renewal is required, could deter suppliers from pursuing MUPs for their products. This could lead to a situation where there are no registered products available, and no products available under MUPs either.

Given all rationale above, **Atlantic salmon should remain as a minor species**. It is essential that the limited range of products available for Aquaculture is not further curtailed through a classification process that impedes access to these products through the MUP pathway.

In general, any changes to species classification must allow a significant adjustment period where-by 'supply permits', or similar, are issued for a period of 5 years to ensure there are no gaps in veterinary medicine supply while changes are implemented.

Sincerely,
Huon Aquaculture Company Pty Ltd

11th October 2024

Australian Melon Association Inc
[redacted]

ABN 36 990 325 012 [redacted]

Working together to build a successful future for the Australian Melon Industry

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

To whom it may concern,

Melons Australia welcomes the opportunity to provide a submission on the APVMA's *Draft guidelines for determining minor use.*

Melons Australia is the Peak Industry Body for the Australian melon industry, including Australian growers of watermelons and muskmelons (rockmelons, honeydews and other specialty melon varieties). Production occurs across all mainland States and in the Northern Territory, from approximately 140 growers, producing on average 220,000 tonnes of fresh melons per year.

We acknowledge that the APVMA plays an extremely important role as Australia's independent, science-based, national regulator of agricultural chemicals and veterinary medicines (agvet chemicals), ensuring chemicals sold in Australia are safe and effective however we wish to flag concern over aspects of the APVMA's draft Guideline for Determining Minor Use.

In particular, the draft guidelines have done little to address issues relating to the need for improved timely access to modern crop protection products, and focused primarily on classifying uses and crops on threshold levels based on value and acreage. Some of our specific concerns are outlined below:

Section 1: Major crops, animals and situations

We note that whether a crop is deemed to be classified as either a minor or major crop is based on current Australian statistics regarding volume of production, area under cultivation and the value of crop, however there is no detail provided as to what those thresholds are and on what basis they are derived. This lack of transparency provides us with little confidence as to whether this decision is based on robust economic modelling determining whether there is a market failure specific to that crop which deems a minor crop classification necessary in order to have access to the chemicals it

requires. Australia constitutes a minor market share of global agvet chemical sales and use and our limited share of the global market can create a disincentive for companies to register agvet chemicals in Australia. We would therefore support the clear development of guidelines based on robust economic modelling to determine which crops and uses can be considered minor use based on the need to effectively address and overcome market failure.

With specific respect to the melon industry we recognise that "Melon (except watermelons)" has until now been classified as a major crop but through the review this has now been changed to melons, without the exception. It is not clear to melons Australia where melons fit within the new classification system ie. whether this means that watermelons are now classified as a minor or major crop? In terms of global production we would argue that Australian melon (watermelons and other melons) production is a small fraction of world production. If we use wheat as a comparison, Australian wheat production makes up approximately 3% of global production[1] compared with Australian watermelon production that makes up approximately 0.1% of global production[2]. If we interpret the changes to the guidelines correctly then both crops (watermelons and wheat) are now classified as major crops, which makes little sense. We would in fact argue that based on these statistics that both rockmelons and watermelons should be classified as minor.

Section 2 – Limited use within a major crop, animal or non-crop situation

With regards to the matrix used to classify uses based on the area, number of plants or animals to be treated and the value of the commodity, there is no reasoning or justification provided for the threshold levels used in the matrix. It would be helpful to understand how the cut-off levels for the low, medium and high were determined. Given the bearing these classifications have on the nature of an application (e.g., information requirements), Melons Australia believes the APVMA needs to provide more detail on the basis for these thresholds before a decision is made. Without such information it is impossible for stakeholders to provide meaningful feedback as to their applicability, or otherwise.

For example, the current APVMA guidance on residue trial numbers indicates 8-12 trials for major crops, 4-6 for minor-major crops (presumably those crops falling into the "*More information required*" category[3]) and two trials for minor crops[4]. A change from minor, or minor-major, to major will cause a significant cost increase from the perspective of data generation to gain, or retain APVMA approvals and will put additional cost burden on the countries producers for no real gain.

Furthermore, Melons Australia would like to understand how the APVMA intends to manage renewals for current minor use permits and has the APVMA undertaken any analysis of the likely impact the new

[1] https://fas.usda.gov/data/production/commodity/0410000
[2] https://www.horticulture.com.au/contentassets/a36fdfa2427d4ad284c426663b06f15c/hort-stats-fruit-22-23.pdf; https://worldostats.com/watermelon-production-by-country-2024/
[3] Table 1 Classification of minor uses Draft Guidelines for Determining Minor Use 2024
[4] https://www.apvma.gov.au/registrations-and-permits/data-requirements/agricultural-data-guidelines/residues-part-5a/specific/residue-trials-permanent-mrls

matrix thresholds and crop classifications might have on future permit renewals, or considered how the renewals process is to be managed in the future? Having such an analysis and outline would give stakeholder industries a clearer grasp of the magnitude of issues in the future.

In short, Melons Australia believes that with the current draft Guideline, the APVMA has missed an opportunity for meaningful reform to the Guidelines, to better reflect the nature of problems relating to chemical access in Australian agriculture. While recognising the legislation references insufficient economic return it is difficult to see how focusing on crop value or acreage addresses this requirement. The fact that many crops, major and minor, currently lack sufficient registered options for endemic pest, disease and weed problems should act as a significant indicator to alert the APVMA to the fact that for many uses registrants have had little or no interest.

Consequently, Melons Australia believes there needs to be greater emphasis on exploring mechanisms on how to more effectively manage minor use and access to appropriate chemistry for future pest management needs.

As such support we would recommend, closely in line with other horticulture industries that:

- The APVMA immediately pause their intent to implement the proposed "guidelines" with the exception of those commodities who are seeking to move from major to minor as they have demonstrated "market failure".
- The APVMA review their process for determining minor and major crops and develop a robust set of guidelines/decision matrix based on economic modelling in relation to market failure to determine if a crop should be considered a minor crop.
- The APVMA provide clear explanation of how the cut-off levels for low, medium and high were determined for value and area in various commodities when considering limited use within a major crop to give industries the opportunity to provide informed feedback.
- The APVMA, in consultation with the crop protection industry, research providers and growers, identify the factors that contribute to insufficient access to crop protection products.

On behalf of the Australian melon industry, I thank the APVMA for this consultation opportunity, allowing us to provide our industry views. I would be happy to discuss any of the content of this submission with you in the progression of this matter.

Yours sincerely,

Johnathon Davey

CEO Melons Australia

Review of guidelines for determining a minor use

Submission from Minor Use Foundation Inc.

The Minor Use Foundation Inc. is pleased to make a further submission to the APVMA's review of guidelines for determining a minor use, following the initial consultation conducted in May-June 2023.

The MUF having considered the proposed new guideline maintains its original recommendation as follows:

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.

We remain of this view because of the reasons outlined in our original submission and further explained throughout this submission, where crops (animals and situations) that suffer from a lack of registered solutions are minor uses.

The MUF key recommendations are:

- The proposed guideline is not necessary and would rather increase regulatory burden and costs for applicants, industry and APVMA.
- The acceptance of a permit application for minor uses should enable producers a pathway to access solutions for needs that lack any or have insufficient crop protection solutions.
- The existing 6A guideline for permits is an appropriate guideline for which to base decisions on minor uses.
- The APVMA should present for consultation criteria used for the purposes of updating the list of major crops and where that list should be for the purposes of determining data guidelines and level of risk assessments necessary (for all uses).
- The APVMA and broader government initiate consultation with producer industries and the commercial sector to seek mechanisms that incentivises the registration of minor uses.

The MUF has prepared both overarching comments for consideration as described in the “General comments” section, as well as specific, technical comments for consideration under Appendix 1. The comments are structured in this way for ease of review, and we remain available and to discuss any aspect of the comments in more detail if useful.

In summary some of the matters we have raised in Appendix 1 include:

- The classification of major crops and minor crops should be separate from that of classifying or determining minor uses.
- While a guideline for determining a minor use may refer to a list of major crops, it should not be the source of that list.
- A list of major crops (animals and situations) should be developed in accordance with OECD guidance and for the primary purpose of establishing data guidelines and levels of assessments necessary for conducting scientific assessments that are commensurate with risk.
- Considerations utilised for classifying crops as major should be aligned across both broadacre and horticultural crops.

- It is inappropriate to classify a crop as a major crop on grounds that it is a representative crop.
- Value of production should not be a consideration in defining minor uses (other than for the purposes of assessing risk to trade and defining major export commodities).
- Industry growth does not automatically translate that a crop is now a major crop.
- If information required in support of an application listed in Section 2 differs from that already required in an application (as contained in a legislative instrument) and if that information would also continue to be required in applications falling under Section 1 and Section 3.
- Provision of further explanation for the listed conditions proposed in Section 2, such as reporting scale of use and efforts to discuss registration with product holders, and if those may also apply to applications falling under Section 1 and Section 3.
- Should economic modeling (Section 3) be pursued that improved guidance be developed and consulted on and that mandated Pre-Application Assistance (PAA) is not necessary.
- Should any of the proposed changes proceed that if amendments to other APVMA materials such as legislative instruments, 6A guidelines, residue guidelines and APVMA definitions will also be required.

The MUF thanks the APVMA for its consideration.

General comments

Despite the current or proposed guideline classifying a use as a minor use, to issue a permit the legislation still requires that *reasonable grounds* exist and the APVMA's current 6A guideline recognises that insufficient registered solutions fulfill this requirement. The legislative definition of a minor use only has applicability to permits and plays no role elsewhere in the legislation or the APVMA's statutory obligations. As previously stated, we believe the current 6A guideline for permits already adequately covers the matter, and this proposed guideline is not required and rather introduces additional and unnecessary regulatory burden.

The focus in considering minor use permit applications should be on the actual problem, that is addressing needs where no or insufficient solutions exist, not matrices or economic modeling. If these unmet needs/uses were major uses, then the commercial sector would be or have already registered products to service these needs. We further believe this is supported by the current legislative definitions of a minor use. The first part of the definition which refers to '*insufficient economic return*' we articulated in our original submission, where uses that do provide sufficient return have registered solutions while those that do not, don't. The second part of the definition in short defines a minor use as a use that has a registered solution but where that solution is currently not available in the market. It would seem counter-intuitive that the absence of any or insufficient solutions in a crop (animal or situation) does not alone qualify as a minor use but rather needs to demonstrate this while the intermittent absence of an existing registered solution in a crop (animal or situation) for a short period of time does. This demonstrates in our view that the Australian government recognises that the purpose of minor use permits is to provide solutions to needs in crops (and animals or situations) where no or insufficient solutions exist.

Furthermore, the APVMA as the national scientific regulator of agricultural and veterinary chemicals is considered better able to determine if a use lacks sufficient registered solutions than otherwise

seeking to determine whether a use will provide a registrant sufficient economic return. Producers (growers) are without doubt the primary group who seek minor use permits from the APVMA, probably accounting for >95% of all minor use permit applications. In our experience, producers would rather have registered solutions than have to pursue a minor use permit. Although, in cases where they do not have sufficient solutions, their needs should be recognised in an efficient and pragmatic manner. Producers only seek a minor use permit when it is genuinely needed, they don't make frivolous applications and only engage with governments when absolutely necessary. If they do make unsuitable applications, then the APVMA has a right to refuse those applications. This requires the regulator to be disseminating clear information, communicating and engaging with producers about the role and purpose of minor use permits, understanding their challenges as producers, and not creating additional regulatory criteria and burden.

Globally regulators are seeking mechanisms in support of enhancing minor use authorisations including where possible a reduction in regulatory burden. We consider that the proposed guideline as it relates particularly to Section 2 and Section 3, introduces additional burden on applicants. Having to obtain declarations from registrants or making economic modeling cases will increase the regulatory burden on both producers and registrants and further delay the consideration and availability of safe and effective solutions. We consider not only will it be difficult for applicants (ie. producers) to obtain the necessary supporting economic information but it also introduces additional burden on the APVMA to assess such information. We note the guideline did not provide any indication as to how sufficient economic return will be determined or what it is.

The ability to seek a minor use permit in our opinion should solely be a decision as to whether a crop (animal or situation) has sufficient registered solutions. For example, consider a pest problem in a crop which does not have a registered solution. The applicant (a producer body) has sufficient information to support that the use would meet the legislative tests of safety, efficacy and trade. The regulator can also identify that the proposed use is unlikely to present any additional risk and often where the product is already registered in many other crops under very similar conditions of use. So, everyone may agree the use is highly likely to meet the legislative requirements of safety, efficacy and trade. However, for producers to access this needed solution they must also address additional requirements that have no relationship to scientific risk assessment or producer need, but rather economics. The primary legislative tests of safety, efficacy, and trade for the issuance of a permit are the same as they are for registration. These additional and introduced tests/criteria are not required if the same proposal was a registration application. Therefore, the regulatory requirements for obtaining a minor use permit are greater than that of registration, and where those have no relationship to a scientific risk assessment of safety, efficacy, or trade.

It is noted that of approximately 1,200 minor use permits issued by the APVMA that close to 90% of those are for use in crops while only 10% are for use in animals. It is well recognised that the low reliance on minor use permits in animals is largely because of a veterinarian's right to prescribe off-label. While we understand veterinarian prescribing rights are outside the AgVet Code as administered by the APVMA, we recommend that the core justification for enabling producers access to solutions for unmet animal and plant health needs should be aligned. It is well recognised that veterinarians when prescribing off-label for minor species and minor uses do so in accordance with the Australian Veterinary Associations *Guidelines for Prescribing Authorizing and Dispensing Veterinary Medicines* (AVA). As part of the AVA guideline, veterinarians may consider off-label (or

unregistered) uses only in circumstances where registered veterinary medicines either do not exist or those registered are ineffective. Therefore, veterinarians are regularly prescribing off-label treatments for minor species and minor uses where no or insufficient registered options exist. The APVMA in our opinion in administering minor use permits in agricultural crops (and situations) needs to take a similar approach to what is the same issue. Such an approach would provide equity across both animal and plant industries through a harmonised principle that off-label uses (either through an APVMA minor use permit or veterinarians prescribing rights) are for needs that have no or insufficient registered solutions. The absence of an aligned principle would seem inequitable to those producers who must undergo additional criteria and tests as proposed in the draft guideline.

The clear broader objective in our opinion should be to reduce the reliance on minor use permits (and veterinarians prescribing off-label) by having more minor uses registered. Although this is not part of the current consultation, we would recommend that the APVMA and broader government in consultation with producer industries and the commercial sector need to be working together to seek mechanisms that incentivises the registration of minor uses. The MUF would be highly supportive and pleased to participate in discussions that progresses this issue.

Sincerely,

Anna Gore

Executive Director

Minor Use Foundation

Appendix 1

The proposed draft guideline contains relatively the same three-tiered approach as the existing guideline. That being where any crop that is not listed in Section 1 is considered by exclusion a minor crop and a minor use. While uses in major crops (listed in Section 1) may still qualify as a minor use if those uses would meet the criteria of either Section 2 or Section 3. The MUF considers the following as the key proposed changes to those tiers:

Section 1 (currently Schedule 1)
- inclusion of lemons, raspberries, blueberries, olives, cucumber, zucchini, lentils and celery as major crops
- removal of maize, pineapples, mushrooms and sunflowers as major crops

Section 2 (currently Schedule 2)
- inclusion of a matrix for determination of a minor use in a major crop based on classifications of area and value for different commodity types

Section 3 (currently Schedule 3)
- the requirement for applicants to undergo Pre-Application Assistance (PAA)

The APVMA stated in its original consultation paper (February 2023) that its proposal was to "*develop a set of well-defined parameters to classify **major and minor uses** and to update the list of **major crops, animals and situations***". The MUF recommends that the APVMA follow the critical elements as recommended by OECD in its guidance document on defining minor uses in particular critical element #2 (Figure 1 below).

Figure 1: Extract from *OECD Guidance Document on Defining Minor Uses of Pesticides*

DEVELOPING A MINOR USE DEFINITION: THE CRITICAL ELEMENTS

In developing a minor use definition aspects as outlined in this document should be fully considered including examining current approaches and definitions, which exist in member countries (Appendix 1). The following are four elements that should be considered in developing, using and maintaining a definition, including the need to consider complementary regulatory incentives to encourage the registration of more minor uses.

1. Development and implementation of minor use definitions should be conscious of and reflect the different factors that result in minor uses. In particular the mechanism(s) should be specifically designed to enable considerations to be made for those uses that do not provide sufficient economic return for an applicant to justify registration of the use.

2. Determinations of what are minor uses derived via an economic return approach should remain independent from determinations of regulatory risk assessment and establishing data requirements of major and minor crops derived via the risk assessment approach.

3. Definitions and mechanism(s) of determining minor uses should be regularly reviewed to ensure that they are current and up to date with the crop protection trends and needs of agricultural producers.

4. Minor use definitions should be complemented by regulatory incentives that are developed to encourage the registration of more minor uses.

Varying opinions commonly arise about what are major & minor crops and minor uses. The drivers for each are quite different as are the purposes for which they are to be used. The drivers, differences and purposes are well described in the OECD guidance document.–The guidance

document states, "*cut-off limits on level of production and dietary intake largely define what commodities are 'minor crops' or major crops' and primarily for the purposes of determining the level of risk assessment (and data) required for a given use*".

The MUF recommends that the APVMA should separate the classification of major crops and minor crops from that of minor uses. This as we will explain further is in our opinion a more suitable approach. This approach is aligned with OECD guidance which also recommended "*it is important to ensure that determinations of what are minor uses remain independent from determinations of regulatory risk assessment and establishing data requirements of major and minor crops. This will ensure a scientifically robust level of regulatory risk assessment is maintained to safeguard users, consumers and the environment irrespective of the use being considered a minor use in a major crop or minor crop"*. In other words, if a minor use presents significant or major exposure, data commensurate to assess that use should still be required be it through registration or a permit, and in a major or minor crop.

The MUF provides further input below firstly on updating the list of major crops and then on the three sections of the proposed guideline for defining a minor use which we do not support.

<u>Updating the list of major crops (Section 1)</u>

The MUF supports the APVMA having a list of major crops (animals and situations). However, the MUF recommends that the APVMA develop the list in accordance with the principles of the OECD guidance noted above. That is where the list be developed for the primary purpose of establishing data guidelines and levels of assessments necessary for conducting scientific assessments that are commensurate with risk. A guideline for determining a minor use may refer to such a list, but it should not be the source of that list.

Presumably, any changes to the current list will have associated changes to other APVMA materials and guidelines and these should be noted. For example, The APVMA *Definition of Terms* mirrors the existing list of crops, animals and situations and would also require amendment. The APVMA residue guidelines on numbers of residue trials includes four separate classes, (i) major, (ii) major/minor, (iii) minor/major and (iv) minor. Considerations may therefore be required if classifications of major/minor and minor/major are also needed.

Proposed classification changes of major and minor crops

While the original consultation paper (February 2023) stated one of its aims was to "*provide criteria to classify major and minor commodities*", there was no discussion or explanation of what criteria was used to classify crops as major crops in Section 1. While Appendix B provided some discussion the reasons appear arbitrary such as *"industry growth"*, *"comparable to other major crops"* or that crops were *"representative crops"*. We have provided comments on each of these aspects further below. However, in absence of any specific criteria it has not been possible to provide input on the proposed revisions as we have not been able to determine how they were derived.

The MUF initially assumed that the matrix in Section 2 of the guideline might be the source of the criteria for classifying major and minor crops. Where outcomes of 'minor' in the matrix would classify a crop as being a minor crop with all other outcomes classifying a crop as a major crop.

However, we tested this assumption based on some of the proposed changes from minor to major and vice versa and this does not appear to be the case, as we will explain.

The move of maize which the MUF supports to a 'minor use' status did not correlate with the matrix in Section 2 as being 'minor'. In submissions received to the first round of consultation it was noted that maize has a production area exceeding >10,000ha (ie. 150,000-170,000ha) and >$100M (ie. $150M) production value. According to the proposed matrix for a broadacre crop this would result in a 'High/High' classification and qualify for consideration under Section 3. In contrast, several of the crops being proposed for reclassification as minor to major crops, such as lemons, celery, cucumber, raspberries, blueberries and zucchini each have production areas less than 5,000ha (Hort Innovation) resulting in either "Medium/Medium" or "Medium/High" classification and qualify for consideration under Section 2. We therefore concluded that the matrix in Section 2 has no relationship to the classification of major crops in Section 1.

Representative crops

The consultation paper implied the status of cucumber, zucchini and celery as a representative crop is a reason to justify their movement to a major crop status. As the APVMA's own guideline on the extrapolation of data notes, representative crops are typically chosen based on (i) production and consumption and (ii) most likely to contain the highest residue. It however must be acknowledged that several crop groups are in themselves quite small in production or contain very few or no major crops. Representative crop selection for the purposes of residues and dietary risk assessment may therefore include commodities with higher consumption than others in the group, not simply because they are considered major in production terms (ie. hectares). This is required to achieve an understanding of the likely residue profile across all members of a crop group. This often results in many crop groups having representative crops that are both major and minor crops, or in some cases exclusively minor crops. For these reasons the MUF considers that it is inappropriate to classify a crop as a major crop solely on the grounds it is a representative crop.

Industry growth

Several proposed changes from a status as a minor to a major crop provided in Appendix B was due to "*growth of the industry*" such as in the case of lemons, blueberries and raspberries. The consultation paper noted that these industries had increased as follows: lemons 1,011ha to 1,742ha, blueberries $53M to >$400M and raspberries are >$150M. Blueberries and raspberries are estimated to be produced on areas of approximately 2,300ha and <2,000ha respectively (Hort Innovation). Industry growth does not automatically translate that a crop is now a major crop.

Regardless of this growth these industries in our opinion all remain minor crops. Further as noted above according to the matrix in Section 2 these would result in either "Medium/Medium" or "Medium/High" classification and qualify as a minor use. We therefore interpret that the proposed guideline might be saying these crops are proposed "major crops" but they are still "minor uses" according to the matrix in Section 2.

Additionally, as stated in our original submission the value of production has little if any bearing on a crop being a major crop and, in our view, should not be a consideration in defining crops as major or minor. High value crops grown on small areas can have the opposite effect where registrants may

avoid situations that represent increased liability risk from otherwise small volume sales (we further discuss value of production below under our response to *Defining minor uses*).

Comparable to other major crops

Other proposed changes from a status as a minor to a major crop were cucumber and zucchini which were stated as "*comparable to other major crops such as capsicum and asparagus"*. It is important as noted above to reflect on industry size. In the case of cucumber, the production area is quite small, potentially estimated at <1,000ha, where approximately 50% of national production is in protected environments totaling only around 100ha (Hort Innovation). Whereas zucchini production at around 40,000 tonnes per annum (Hort Innovation) is likely to equate to roughly 2,500ha (based on 16 tonnes/ha). Capsicum production in Australia is estimated to be around 1,700ha, while asparagus is estimated to be around 1,100ha (based on average 5 tonnes/ha from 5,296 tonnes and $59M)(Hort Innovation). Given all these four crops would meet the criteria of the proposed Section 2 we consider that not only should cucumber and zucchini remain as minor crops, but consideration should also be provided to reclassifying both capsicums and asparagus as minor crops.

Other country regulators criteria for defining minor/major crops and minor uses

In our original submission the MUF noted that the U.S. EPA defines a minor crop (or specialty crop) as one produced on an area less than 300,000 acres. The MUF would also like to draw the APVMA's attention to a recent survey published by the European Minor Uses Coordination Facility (MUCF). The survey report noted that twenty-one of twenty-four (21/24) countries utilise cultivation area as the criteria for classifying a crop as a minor crop. Different areas are used amongst countries although the following table provides a summary of some country classifications.

Table 1: summary of some European country classifications for minor crops

Area	Country
<20,000ha	France & Italy
<10,000ha	Austria, Czech Republic, Estonia[a], Germany[b], Spain, Ireland, Latvia, Portugal & Slovakia
<8,000ha	Finland
<6,000ha	Hungary
<5,000ha	Lithuania[b] and The Netherlands

[a] Estonia classify a minor crop as <1% of total national production, which is otherwise <10,000ha based on a national production area of 987,000ha.
[b] Lithuania and Germany are currently considering increasing their definitions from 5,000ha to 10,000ha and from 10,000ha to 50,000ha respectively.

The remaining countries surveyed either consider (i) dietary consumption, (ii) list major crops and exclusions are by default minor crops, (iii) list minor crops or (iv) consider a % of the total national agricultural production (ie. <2% Poland). Of those countries who list individual major crops, it is noted that the United Kingdom have defined minor crops as *"all crops are minor apart from grass, oats, barley, forage maize, wheat, sugar beet, dry harvest field beans, canola & potatoes (other than*

seed potatoes)". It was also noted that Sweden has defined all fruit, vegetables and ornamentals as minor crops.

Defining minor uses (Sections 1, 2 and 3)

We understand that where a crop is not listed as a major crop it is then by exclusion considered a minor crop and a minor use. This approach is suitable, and often utilised by many regulators, such as many European regulators as noted above. Although as we have stated above, we recommend that a list of major crops be developed primarily for the purposes of determining data guidelines and level of risk assessments necessary. As the current consultation does not appear to have explained the criteria for determining the proposed list of major crops the APVMA should further consult on the criteria, outline suggested changes and explain when and how the list will be used for regulatory purposes. Further, while a guideline for determining a minor use may refer to a list of major crops, it should not be the source of that list.

The MUF does not support the approaches outlined in Section 2 or Section 3. As explained, we consider the focus of a guideline should be on enabling minor use permit applications for uses that lack any or have insufficient crop protection solutions, be they in minor or major crops. This approach is already explained in the current 6A guideline for permits but could be improved to provide greater clarity for applicants. Such as for those situations where registered alternatives may exist and under what circumstances and/or what evidence is required to demonstrate those registered products are either unsuitable or ineffective. Discussing and consulting with producer groups and industry on approaches to this would in our opinion be beneficial.

The MUCF report noted above also surveyed and discussed different approaches and criteria used by European regulators in defining minor uses. Of twenty-one countries it is noted that eighteen of those deem that a use in a minor crop is also a minor use. The report also states "*Several countries have implemented additional criteria to define a minor use on or in a major crop. For example, if a use on a major crop concerns a small crop production acreage (eg. a pest that only occurs on a small scale), the use is in the public interest, or there is a limited or non-existent number of plant protection solutions available to control the harmful organism. These uses on a major crop can be considered minor uses in these countries*".

The MUF contends that these additional criteria in place in several European countries goes to the core of what are minor uses. For example, '*a pest that only occurs on a small scale*' is very likely to be a minor use and without any or insufficient registered solutions. As too are situations where '*there is a limited or non-existent number of plant protection solutions available to control the harmful organism'*. We consider that the MUF suggested approach has similar principles. Whereby a general list of major crops is used as a guide for accepting that all other crops are by exclusion minor crops and minor uses, and where minor use considerations are also applicable to situations for uses that lack any or have insufficient crop protection solutions, be they in minor or major crops.

While the MUF does not support the approaches outlined in Section 2 or Section 3, we find it important to provide further reasons and input for consideration.

Value of production

As explained earlier, in our view, the value of production should not be a consideration in defining minor uses. Although we do not object that value of production for export commodities may be a consideration when the APVMA is assessing trade risks from uses in major export commodities, which is a risk assessment consideration, not a minor use consideration.

Value of production was not cited in the MUCF report as a criterion in use by any European countries in defining crops or uses as major or minor. In support of this the following table has been reproduced from the MUCF report depicting the minor crop production value to the minor crop total acreage as a percentage in certain European countries. The report specifically stated, "*Although comprising less than 4% of the totally produced crops acreage, minor crops production contributes more than 40% to the countries total crop production value in the case of Finland and the United Kingdom*". This demonstrates clearly why considering the value of production is not an appropriate criterion for defining major crops or uses.

Table 1: Minor crop production value to the minor crop total acreage as a percentage in certain European countries (MUCF)

Percentage of acreage of minor crops (% of the total crop acreage)	Percentage of production value of minor crops (% of the total crop production value)	Country
13%	30.3%	Estonia
6%	12.0%	Slovakia
4%	43.4%	United Kingdom
4%	48.8%	Finland
2%	26.9%	France
2%	15.2%	Switzerland
1%	7.3%	Lithuania
1%	20.9%	Sweden

When examining Section 2 of the proposed guideline, our interpretation was that several current and proposed major crops are likely to automatically qualify under Section 2 even where use would involve 100% of that crop's production area (some examples were provided above). We believe this may create confusion between Section 1 and Section 2 for many crops and producers. Our interpretation of the matrix is that a use would be accepted as a minor use under Section 2 if it resulted in a matrix outcome of "*More information required*" which briefly encompasses either:

- broadacre crop uses that are:
    - less than 10,000 ha
      OR
    - for uses exceeding 10,000 ha less than $100M in production value

- horticultural crop uses that are:

- less than 5,000ha or 1 million trees
  OR
- if greater than 5,000ha or 1 million trees less than $75M in production value.

For reasons stated above we do not consider value as an indication of a crops status as major or minor. However, area values could be considered to develop the list of crops deemed to be major crops. Although we would encourage the APVMA to consider the following:

- It is not clear why the values chosen differ between broadacre and horticultural crop uses, although it is our opinion that they should align unless reasons can be provided why they should differ,
- It is noted that the US utilises >300,000 acres and several major European countries utilise areas such as >10,000ha and >20,000ha and Germany is considering extending to >50,000ha.

Within Section 2 of the proposed guideline, it also listed several types of information that may be included to support the minor use permit application, such as:

(i) scale of use
(ii) a declaration from registrants that the use is not commercially viable
(iii) availability of management options, problem distribution and frequency,
(iv) evidence of industry need, and,
(v) evidence of a lack of suitable registered alternatives.

Several of these are interrelated. For example, scale of use should discuss aspects of problem distribution and frequency, and evidence of lack of suitable registered alternatives should discuss availability of management options and industry need. The MUF notes that Division 4 of the APVMA's *Application Requirements* legislative instrument already requires information on "*an estimate of the extent to which the product will be used*" and "*an explanation of why no currently registered product would be suitable or effective for that use*". Additionally, as noted in our original submission the existing 6A guideline for permits also provides further guidance on the latter. Therefore, it is not clear how items (i), (iii), (iv) and (v) above differ from the current legislative instrument and/or 6A guideline.

In terms of obtaining a declaration from registrants, it is unclear what benefit (or weight of support) this would genuinely provide and if it is required to be obtained from all, some or just one product registrant(s). Product registrants may also choose not to respond or see it as a low (*minor*) priority, placing applicants in a potentially difficult and delayed situation. As noted earlier globally regulators are seeking where possible to reduce regulatory burden in support of enhancing minor use authorisations although this proposed requirement would appear to be increasing burden on the applicant, registrants and the APVMA.

It was therefore not clear if the information proposed above (i-v) would be included in an amended legislative instrument, 6A guideline or both. Furthermore, as this list (i-v) only appeared in Section 2 of the proposed guideline it was not clear if this information was intended to also be applicable to applications also falling under Section 1 and Section 3. It is noted that the above requirements in Division 4 of the legislative instrument currently apply to all applications seeking a minor use permit. The above aspects raised would benefit from clarification and explanation if the APVMA continues to pursue this model.

Three conditions that may be applied to a permit were also proposed although it was not clear if these conditions only applied to a permit falling under Section 2, or if they may also apply to a minor use falling under Section 1 and Section 3. The MUF does not understand the rationale for at least two of these conditions. If the use has already been deemed to be a minor use, and presumably in issuing the permit it satisfied the legislative criteria, why would the permit holder have to report scale of use or provide efforts to discuss registration with product holders. In some cases, permits are held by peak industry bodies or associations and allow use by persons generally. It would be somewhat difficult for permit holders to obtain reliable information on scale of use, and again why is it needed for a use that has been found acceptable. Should ongoing evidence be required from registrants, as above is this required to be obtained from all, some or just one. These suggested conditions require further explanation.

Section 3 of the guideline was proposed for those instances where the limits in Section 2 are exceeded. It proposes to require an applicant to first seek Pre-Application Assistance (PAA) and provide economic modeling to justify that the use would not produce sufficient economic return. The MUF does not support this approach for several reasons. As mentioned in our original submission and again above, this information is difficult to obtain, and probably difficult to decide if sufficient economic return exists, as different situations and circumstances need to be considered and in short 'not all are equal'. Further, as noted earlier, the proposed guideline did not discuss or provide any reasoning as to what is considered sufficient economic return.

The requirement to mandate a PAA is also not supported. It is also questioned if it is feasible to mandate PAA without supporting legislation. There are several matters which we would like to highlight for consideration should the APVMA continue to pursue this approach.

1. The APVMA should provide greater guidance on what information is needed in support of economic modeling. If those matters listed in the proposed guideline are required, then the applicant should provide those details on lodgment of their permit application and the APVMA should assess the application in the usual manner.
2. Creating a 'pre-application' process will only delay an applicant's request. Presuming the APVMA will only seek to consider if the need is a minor use under this process. It is noted that a Tier 2 PAA has a timeframe of 2 months. The applicant must then lodge their application and await further consideration of the normal risk assessment. The process should follow that as described in Point 1 above – single application where the APVMA conducts both its usual risk assessment and economic considerations for minor use status at the same time, in the same application.
3. An application for a minor use permit costs $350. While the minimum cost for a Tier 2 PPA is currently $962.50. It is noted that recently released proposed fee changes would see a minor use permit rise to $500 and a Tier 2 PAA rise to $3,657.50 from July 2025. Minor use permit applications are not eligible for any PAA rebate. It is inequitable to not only provide a rebate, but also to seek a fee of either $962.50 or $3,657.50, to get a ruling if one can then make application for what is a $350 or $500 permit.

The proposed guideline suggesting PAA also appears to imply that product holders would be seeking these minor use permit considerations not producers, where it states, '*the holder may apply for a minor use permit*'. As stated earlier the MUF understands that 95% of permit applicants are

producers. The MUF is not sure what the APVMA is seeking to achieve by introducing mandatory PAA for minor use permits.

References

AVA. Guidelines for Prescribing, Authorising and Dispensing Veterinary Medicines (2023) Ed. M.P.Bond, Australian Veterinary Association Ltd. Retrieved from AVA: https://www.ava.com.au/siteassets/resources/prescribing-guidelines/guidelines-for-prescribing-authorising-and-dispensing-veterinary-medicines-october-2023.pdf

Hort Innovation. Australian Horticulture Statistics Handbook 2022/23. Retrieved from Hort Innovation: https://www.horticulture.com.au/growers/help-your-business-grow/research-reports-publications-fact-sheets-and-more/australian-horticulture-statistics-handbook/

OECD. OECD Guidance Document on Defining Minor Uses of Pesticides. Retrieved from OECD: https://www.oecd.org/en/publications/oecd-guidance-document-on-defining-minor-uses-of-pesticides_9789264221703-en.html

MUCF. Survey 2022 compiled data & information, on Minor Uses work in the EU countries plus Norway, Switzerland, and the United Kingdom. MUCF Secretariat (2023). Retrieved from: https://minoruses.eu/media/files/resources/MUCF_MU_Survey_2022_Compiled_Information_final.pdf

National Farmers Federation | Horticulture Council

11 October 2024

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

By email: enquiries@apvma.gov.au

To the Director,

RE: Review of guidelines for determining a minor use

The NFF Horticulture Council (the Council) on behalf of the wider national horticulture industry, would like to thank you for the opportunity to provide comment on the draft guidelines for determining a minor use, with a view to ensuring they remain fit-for-purpose in a modern regulatory environment.

The Council is the recognised peak body for forming policy and advocating on behalf of the national horticulture industry. Established in 2017, it now comprises 20 national commodity and state-based horticulture bodies, who together represent the full breadth of an incredibly diverse industry.

The Council is a strong supporter of a rigorous science based regulatory system for agricultural and veterinary chemicals. We recognise that the APVMA plays an important role in ensuring that chemicals sold and used in Australia are both safe and effective. That said, the regulatory system must ensure equitable access to crop protection products and not act as a barrier to our global competitiveness. 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. This diversity also means that the range of crop protection products utilised by the sector is significant and varies widely.

Due to the relatively small scale of horticulture production in the global context we are a less profitable market for chemical companies and therefore an appropriately resourced and managed minor use program is critical to overcoming that market failure. We understand that horticulture as a whole, holds the largest number of minor use permits and as such our sector is most affected by these proposed guidelines.

We draw your attention to the submission from the NFF as well as submissions from our members Berries Australia, AUSVEG and Citrus Australia who consistently point out that the consultation process followed has been inadequate and the proposed guidelines deeply flawed. We also reiterate that the

NFF House
14-16 Brisbane Ave.
Barton ACT 2600
Locked Bag 9
Kingston ACT 2600
(02) 6269 5666
nff.org.au
ABN 77 097 140 166

implications from this poorly thought through proposal on our sector are significant. We do not want to pick winners and losers in the minor use lottery, but rather have a robust and defensible set of guidelines that address the core issue which is market failure. The proposed new guidelines do nothing to make things clearer for industry and seem to have been developed without any underlying logic. It is also disappointing that the issues raised as part of the previous consultation seem to have been ignored.

There is no value in rehashing the points made in the aforementioned submissions but please note that the Council fully endorses the points raised and in particular the following recommendations:

1. That the APVMA immediately pause their intent to implement the proposed "guidelines" with the exception of those commodities who are seeking to move from major to minor as they have demonstrated "market failure".
2. That the APVMA, in consultation with the crop protection industry, research providers and growers, identify the factors that contribute to insufficient access to crop protection products
3. That the APVMA develop a robust set of guidelines or decision matrix based on economic modelling in relation to market failure to determine if a crop should be considered a minor crop.
4. That any intent to revoke the minor status of a crop should be accompanied by a five-year transition plan developed in consultation with the affected industry.

The Council has recently established a taskforce focused on chemical access and use and we invite the APVMA to work with us to improve chemical access for the horticulture sector and in particular develop a robust and defensible model for determining minor use.

To discuss further, including to arrange an opportunity to join a future meeting of the taskforce, please be in contact with Richard Shannon, Executive Officer to the Council either by email at hortcouncil@nff.org.au or phone on 0448 860 630.

Yours sincerely,

JOLYON BURNETT
Chair
NFF Horticulture Council

National Farmers Federation

11 October 2024

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

Via email: enquiries@apvma.gov.au

To whom it may concern,

RE: NFF submission on the APVMA's Draft Guidelines for determining minor use

The National Farmers' Federation (NFF) welcomes the opportunity to provide a submission on the APVMA's *Draft guidelines for determining minor use* (the Draft Guidelines).

The NFF was established in 1979 as the national peak body representing farmers and the agriculture sector more broadly, across Australia. The NFF's membership comprises all of Australia's major agricultural commodities across the length and the breadth of the supply chain.

The NFF acknowledges that the APVMA plays an extremely important role as Australia's independent, science-based, national regulator of agricultural chemicals and veterinary medicines (agvet chemicals), ensuring chemicals sold in Australia are safe and effective.

Australian farmers participate in globally competitive markets and it is important that they have access to innovative tools and technology – including agvet chemicals – that allow them to produce high quality commodities in a cost-effective manner.

Australia constitutes a minor market share of global agvet chemical sales and use. In this context, Australian farmers face an ongoing barrier to accessing agvet chemicals, as our limited share of the global market can create a disincentive for companies to register agvet chemicals in Australia.

Minor Use Permits (MUPs) play an invaluable role in addressing known market failures and ensuring Australian farmers have access to safe and effective agvet chemicals where full product registration is not economically viable. This is particularly important for producers of crops and animals that comprise a smaller proportion of the Australian and international market, in terms of scale, volume, and value of production. These sectors, including the horticulture industry, suffer from a high level of market failure in terms of access to agvet chemicals through traditional product registration and thereby rely on MUPs as a crucial pathway to access agvet chemicals that meet producers' diverse and discrete needs.

NFF House,
14-16 Brisbane Ave.
Barton ACT 2600

Locked Bag 9
Kingston ACT 2604

T (02) 6269 5666
www.nff.org.au
ABN 77 097 140 166

MUPs are also relevant to producers of major commodities such as grains, given specific agvet chemical requirements vary significantly based on location, ambient conditions, and other factors.

The NFF acknowledges the significant changes in the agricultural industry since the APVMA's minor use guidelines last underwent major updates. Innovation, environmental factors, market dynamics and economic pressures mean minor and major crops naturally ebb and flow in terms of the scale and value of production across Australia.

The NFF supports the recategorisation of four commodities from major to minor crops as suggested by the APVMA in the Draft Guidelines, recognising that in most cases this has been requested or supported by representatives of those commodities.

However, it is important to note that recategorizing any crop from minor to major comes with substantial risks to industry, farmers, and the broader Australian community.

The NFF holds some concern that the APVMA developed the Draft Guidelines, and particularly the proposed changes to the list of major crops, without substantive consultation and engagement with bodies representing those commodities set to be recategorised from minor to major crops. While the growth of these commodities and their increased value or scale of production may make the introduction or registration of agvet chemical products into the Australian market more economically viable, this is a best-case scenario and will likely only occur in a limited number of situations.

Furthermore, seasonal or short-term global market fluctuations can contribute to a crop's value or scale of production being inflated to the point where it is comparable to a major crop. In these cases, a long-term perspective is needed when determining whether a crop should be categorised as major or minor, avoiding a scenario whereby a previously minor crop is inflated to a major crop by a transient effect.

The NFF believes the APVMA must better articulate its reasons and evidence for determining whether a crop is minor or major, and proactively engage with potentially affected industries to understand their agvet chemical needs and usages prior to the types of major changes denoted in the Draft Guidelines.

Secondly, while the NFF recognises that minor uses may occur within a major crop, animal, or situation, the Draft Guidelines propose an increased regulatory burden in many MUP applications (or renewals, in the case of a hitherto minor crop being recategorised as a major crop). The Draft Guidelines provide a matrix of the "Value of commodity" alongside the "Area/number of plants/number of animals to be treated (per annum)" to determine scenarios in which minor uses may occur. However, the standards used in this matrix appear arbitrary and require further explanation.

The NFF has also heard concern over a lack of detail in the Draft Guidelines over exactly what further information will be required by the APVMA in support of MUP applications and renewals. A lack of guidance around specific information requirements has historically resulted in MUP holders or registrants providing irrelevant or unneeded

NFF House,
14-16 Brisbane Ave.
Barton ACT 2600

Locked Bag 9
Kingston ACT 2604

T (02) 6269 5666
www.nff.org.au
ABN 77 097 140 166

information to APVMA in support of applications or renewals, further increasing data costs.

The NFF urges the APVMA to deliver straightforward advice and guidelines around what data is required to support a MUP application or renewal, particularly regarding whether a use is minor or major, to reduce regulatory burden on applicants.

The disadvantages faced by Australian farmers in accessing chemicals caused by the small size of the Australian market have been heightened in recent years by increasing data burdens for agvet chemical registrants, while the cost of registrations is likely to increase further (2024 APVMA CRIS Review). There has simultaneously been an increase in critical delays of APVMA processing MUP applications and renewals, while the APVMA's own efforts to facilitate the transition of agvet chemicals from MUPs to full label registrations has delivered only limited success.

Given this confluence of factors, the NFF is deeply concerned at the prospect of commodities losing access to crucial agvet chemicals upon their recategorization from minor to major crops in the new Draft Guidelines.

It is imperative that the APVMA provides an effective mechanism to incentivise full product registration of current MUPs in situations where an agvet chemical is critical to the production of crops or animals set to be recategorised as major.

Accordingly, the NFF urges the APVMA to develop a long-term transition plan and proactively engage with MUP holders and registrants to ensure that no key product applications or uses are lost under the new guidelines.

The NFF also notes with particular concern the proposed inclusion of salmonids as a major animal under the Draft Guidelines. While the NFF acknowledges, as the APVMA states, that minor uses can still occur in a major animal, the increasing regulatory burden of demonstrating that a proposed use will be minor is concerning. Besides the additional time and cost of providing this information, salmonid vaccines must be developed in rapid timeframes and quickly become outdated or ineffective. Unlike in other animals, the additional time required to meet APVMA information requirements under the Draft Guidelines could mean that vaccines are not made available in the required timeframe. This could have disastrous consequences for the industry and farmers.

In summation, the NFF requests that the APVMA:

1. Clearly articulates the factors and assumptions behind categorising a crop or animal as minor or major, and proactively engages with recategorised industries,

2. Delivers further guidance on what information will be required for both MUP applications and renewals and full product registrations, to reduce the data burden disincentivising applicants,

NFF House,
14-16 Brisbane Ave.
Barton ACT 2600

Locked Bag 9
Kingston ACT 2604

T (02) 6269 5666
www.nff.org.au
ABN 77 097 140 166

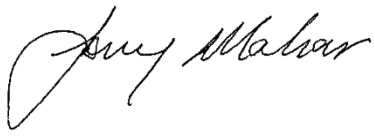
National Farmers Federation

3. Facilitates a straightforward path for transition from MUPs to full product registrations to ensure farmers retain access to crucial agvet chemicals,

4. Develops a long-term transition plan including collaboration with industry and permit holders to minimise and avoid negative outcomes, particularly the loss of critical agvet chemicals.

Thank you for the opportunity to provide a submission to this process. The policy contact for this matter is Mr Zac Rayson, Senior Policy Officer (Rural Affairs), via e-mail: zrayson@nff.org.au or phone: (02) 6269 5666.

Yours sincerely,



TONY MAHAR
Chief Executive Officer

NFF House,
14-16 Brisbane Ave.
Barton ACT 2600

Locked Bag 9
Kingston ACT 2604

T (02) 6269 5666
www.nff.org.au
ABN 77 097 140 166

12 September 2024

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

Via Email: enquiries@apvma.gov.au

Draft Guidelines for Determining a Minor Use

To whom it may concern

I write in response to a request for comments on the proposed set of well-defined parameters to classify major and minor uses and to update the list of major crops, animals and situations.

Unless otherwise stated, this response deals with minor uses as it relates to grain crops (cereal grains, pulses and oilseeds) only.

1. National Working Party on Grain Protection

This submission is presented on behalf of the Australian grain industry by the National Working Party on Grain Protection (NWPGP).

The NWPGP:

- Is the industry body responsible for providing management and leadership to industry in the areas of post-harvest storage, chemical use, market requirements and chemical regulations.
- Is facilitated by Grain Trade Australia and the Chair is funded by Grains Australia.
- Has members across the entire grain supply chain.
- Hosts an annual conference providing participants with the latest research and developments, in the area of post-harvest storage and hygiene, chemical usage and outturn tolerances, international and domestic market requirements, and regulations.
- Co-ordinates and provides government with industry views on chemicals in use on grain and associated products.
- For further details, refer to http://www.graintrade.org.au/nwpgp

2. Industry Views on Minor Uses

Industry supports the intent of the minor use program since its development, and its continuation to "allow for the legal use of Agvet chemicals in situations where registration of the product would not produce sufficient economic return".

One main rider for that support is that when considering a chemical registration under the minor use program, market risks in terms of maximum residue limits (MRLs) are considered and where potential risks arise, industry continues to be consulted.

3. Classification of minor uses based on treatment volume and value of commodity

It is unclear how the cited figures of "Area" and "Value" were determined to develop the classification criteria for a minor crop, as per Table 1 and Table 2. However, at face value, the figures and criteria appear suitable based on the available information.

4. Proposed Changes to the list of major crops

The revised list as outlined under Appendix A "Proposed changes to the list of major crops, animals and situations" is fully supported. The revised list appears to more closely align with APVMA/Codex Crop Groups and should lead to greater clarity.

Similarly, industry notes and supports the comments and/or reasons for changes to the list in Appendix B for Cereal Rye, Maize, Lentils, Sunflowers and Peanuts.

Thank you for your consideration of this submission. Should you have any questions on this submission please do not hesitate to contact me.

Regards

Gerard McMullen

Chair
National Working Party on Grain Protection
Address : 76 Bruce Street, Coburg VIC 3058, Australia
[redacted] [redacted]
[redacted] | www.graintrade.org.au/nwpgp

Produced through Grains Australia Limited funding of this activity

PETUNA PTY LTD

Submission to the Australian Pesticides and Veterinary Medicines Authority review of draft guidelines for determining a minor use

PROUDLY TASMANIAN SINCE 1949

PETUNA AQUACULTURE PTY LTD ACN 009 485 581

PO BOX 72E EAST DEVONPORT TASMANIA 7310 | PHONE 03 6421 9111

www.petuna.com

Director, Permits and Minor Use
Australian Pesticides and Veterinary Medicines Authority

Submitted via email: enquiries@apvma..gov.au on Friday, 11 October 2024

Dear Director,

Petuna Aquaculture would like to take this opportunity to provide its views in relation to the development of the 'Draft guidelines for minor use' (draft guidelines) by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Summary

1. Petuna Aquaculture opposes the proposal to list salmonids as a major species and suggest that salmonids should remain as a minor species.
2. We believe that this particular change in the draft guidelines will have counterproductive repercussions and will not lead to any benefits to safer use of product.
3. The major changes in the draft guidelines lack transparency, evidence, detail, and consistent reasoning.
4. The impacts of such a significant change in regulatory requirements have not been assessed adequately.
5. The proposal increases costs to the industry, with no positive change to the safety and efficacy of the products that we use. The changes act as a deterrent and would result in poorer welfare outcomes. The industry historically has proactively invested in development of products (in particular vaccines) and reformulated to optimise in-field efficacy. This process would inhibit this proactive approach.

Preface

The ability to access safe and effective veterinary medicines is critical for the salmon industry. It ensures the health and welfare of our fish and the delivery of a premium product to our customers that complies with food safety regulations.

The salmon industry is particularly vulnerable to health and biosecurity risks and the industry only has an extremely limited range of products available to manage those risks (including vetchem currently used under a 'minor use permit' (**MUP**)).

Further restricting the available options to the salmon industry by making acquiring MUPs more onerous and time consuming would be detrimental to the industry and potentially affect the health and welfare of fish.

Veterinary medicine use in salmon is very different to that of terrestrial animals and all products within our industry are currently used as minor applications or under veterinary prescription. This is due to sporadic use, use only at certain sites or situations, small volumes used, small numbers of fish used on, or products that are regularly refined and updated. Due to these reasons the registration of products for salmon is unviable to the industry.

Additionally, all vaccines for the industry are developed locally in Tasmania through collaborative government and industry research and development. These products are bespoke and subject to regular changes to accommodate new antigens and other recipe

improvements, such as dose, adjuvant volumes, adjuvant types. If full registration of these products is required it would become likely that registered products would be superseded rapidly, making the process unfeasible.

The margins on vaccines are such that the costs of registration would make vaccines uneconomical to pursue for industry developers and manufacturers. The market is not currently scalable and the increasing cost of regulation across the board further impinges on economics for the industry.

It should also be noted that the definition of the term 'salmonids' within the guidelines needs to be addressed. The term 'salmonids' encompasses both species 'trout' and 'salmon.' This is equivalent to using the term 'poultry' or 'ruminants' (i.e. refers to a group of animal species farmed at a different scale). Production of neither salmon or trout should not be considered 'major' as this species is farmed in very small quantities, therefore, the term used in the guidelines should be very specific: Atlantic Salmon. Petuna Aquaculture produces a small volume of trout and would like to highlight the importance of making this distinction, as vaccine products are species specific and there are significant volume differences between products used on trout and salmon.

Determining a minor use

The change to make salmon a 'major' species would not achieve any practical or beneficial outcomes for the salmon industry, its manufacturers, suppliers, products or consumers. It would instead create an administrative and financial burden on the industry's suppliers (some are small and medium enterprises) as almost every product the industry currently uses will need to be retained under a MUP because of the insufficient economic returns to register.

Though industry would argue that all its veterinary tools would meet the concept of insufficient economic return, it is a great concern that there would be a need to repeatedly justify and furnish all the necessary information to satisfy Section 3 of the guidelines every time a MUP or renewal is required. This in turn, could deter suppliers from considering MUPs for their products, which could lead to a situation where available products, either Registered or under MUPs, are extremely limited.

We set out below our specific comments in relation to each section of the draft guidelines.

Guidance key for eligibility

There are no changes to this section that Petuna wishes to raise.

Section 1 – major crops, animals and situations

"Salmonids" are listed in major animal species – Petuna Aquaculture does not support this change and also wishes to raise that "Salmonids" needs to be further defined, as rainbow trout may also be captured in this definition. This is discussed further above.

Section 2 – limited use within a major crop, animal or non-crop situation

Table 2 classifications do not include salmonids. We suggest that this table is revisited, and that there is evidence presented for the numbers, tonnages, values and classifications provided for salmonids. Additionally, we suggest that there are clearer definitions around "value" of the commodity. These were not included in the last published guidance updated in 2021[1], and if these classifications are going to be used henceforth, then we would expect that the methods used to develop this matrix is published in order to provide adequate

commentary. Petuna submits that it is not reasonable that such a major change is suggested, without providing a transparent method and rationale for the new table.

Section 3

In Petuna's view, "sufficient economic return" is poorly defined, and for each business, there are variations to the expected profit margins to deem the commercial products viable. Historically the salmon industry have invested into the research and development of vaccines through the Centre of Excellence in Aquatic Animal Health and Vaccines, and have contracted the commercialisation and manufacturing of the vaccines. It is also difficult to estimate the in-kind contributions and value of the IP and know-how from the commercial manufacturers. The salmon industry have historically changed the formulations of vaccines regularly, including the addition of antigens, adjuvant types and formulas in the dossier to optimise recipes. This flexibility is critical for the salmon industry. This is simply due to the bespoke and low volume nature of the vaccines – this will not change, and it is best to recognise this reality upfront and simply retain the species group and its products as minor.

Appendix A and B

This section shows the proposed changes only by "red" font or strikethrough and includes a short paragraph on the aquaculture species proposal with somewhat subjective wording on the size of the industry. The reference used is ABARES 2023, this includes salmon and trout production (together) and does not include any future trajectory of the industry. The focus of the wording on Page 19, is on the growth of the industry over the last 20 years and "value" of the industry. The reality is, that we foresee no significant growth in volume in the near future.

It is our contention that salmon is a minor species when compared against the other animal species:

1. The volume share of fresh protein in Australia is 38.2% chicken, 24.9% beef, 17.8% pork, 7.4% lamb and 1.2% salmon;
2. Beef produces 2,250,000mT, pork 480,000mT, lamb 621,000mT, chicken 1,256,000mT, whereas salmon produces 82,000mT, a quantum less.

In addition, the apparent reasoning behind moving certain groups from major to minor must be considered and the decision as regards salmonids assessed in light of the indicators in those cases:

1. Pineapples and mushrooms are two groups slated for movement to minor listing;
2. Reasoning included relatively high-value low volume, few growers and limited cropping area;
3. These arguments also apply to salmon – a sector of low volume (compared to other animal proteins), just three growers and limited growing areas geographically restricted – the combined surface areas of our pens amount to just over 100 hectares; compared to mushrooms at 132 hectares;
4. To add some other context these proposed minor species produce over 70,000mT each and mushrooms are consumed by the Australian public at a rate 50% higher than salmon (3kg per capita per year).

In addition, it should be noted that many registered chemicals for horticulture can be used across many different cropping use-cases; and similarly, products (including vaccines) in lamb/beef/goat; and chicken/duck/turkey/other poultry. As such, the cost of registration and development can be spread across several industries, this is not the case for products used in the salmon industry. This should be accounted for in the guidelines in either the rationale or the matrix for Appendix A or B.

Given the above comparisons, Petuna submits that the overwhelming evidence points to salmon being a minor species.

Thank you

On behalf of Petuna, we express our appreciation to the APVMA for the opportunity to provide input on the 'Draft Guidelines for Minor Use.'

As a company dedicated to sustainable aquaculture, Petuna values the importance of ensuring that the minor use of pesticides and veterinary medicines aligns with environmental safety and the well-being of our aquatic ecosystems. We believe these guidelines are critical in supporting responsible practices within our industry.

Petuna is committed to sustainable aquaculture practices and ensuring Tasmania's unique marine ecosystems are protected. We recognise the importance of these guidelines in fostering a responsible approach to the use of pesticides and veterinary medicines that supports both industry growth and environmental stewardship.

Thank you once again for this opportunity, and we welcome any further discussions or information you may require.

Salmon TASMANIA

+61 0403 882 283
admin@salmontas.au
salmontasmania.au
83 Salamanca Place,
Battery Point, Tas. 7004

10th October 2024

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

Dear Director,

Salmon Tasmania welcomes the opportunity to provide its views in relation to the development of the *'Draft Guidelines for Determining Minor Use'* by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Salmon Tasmania is a peak industry body representing the interests of Tasmanian salmon farmers, within the Australian aquaculture sector. Salmon Tasmania's members are industry leaders dedicated to sustainable and responsible aquaculture practices within the local salmon farming community.

This submission has been prepared by Salmon Tasmania on behalf of our members, the major operators in Tasmania, being Petuna Aquaculture, Tassal Operations, and Huon Aquaculture.

The following paragraphs outline the direct concerns Salmon Tasmania and its members have with the current draft guidelines and we encourage the APVMA to consider these views and concerns when finalising the guidance for determining minor use.

Salmon Tasmania submission

Summary

- Salmon Tasmania, on behalf of its members, opposes the proposal to list 'Salmonids' as a major species as suggested in the draft guidelines for minor use. Salmonids should remain a minor species.
- The proposal to list salmonids a major species would not have productive or beneficial outcomes for the industry, and the draft guidelines for determining minor use lacks detail and clear, consistent reasoning for the reassignment of this animal group. Such a significant regulatory change has not been adequately reviewed and assessed for its impact on the industry.
- The salmon farming sector is subject to the most stringent and numerous of regulations of any farming sector in Australia, on top of which the industry does not see any significant volume of growth going forward. The welfare of the industry depends on margin improvement and cost control. This proposal increases costs with no discernible change to

+61 0403 882 283
admin@salmontas.au
salmontasmania.au
83 Salamanca Place,
Battery Point, Tas. 7004

the safety and efficacy of the products used by the industry. In fact, this proposal would result in poorer welfare outcomes and increased costs.

Preface

- The ability to access safe and effective veterinary medicines is critical for the salmon industry. It ensures the health and welfare of our fish and the delivery of a premium product to our customers that complies with food safety regulations. The salmon industry is particularly vulnerable to health and biosecurity risks given the environment it operates in and the industry only has an extremely limited range of products available to manage those risks (including vetchem) currently used under a 'minor use permit').
- This situation is very different to other major species which have numerous Registered products available to manage health issues. Further restricting the available options to the salmon industry by making acquiring MUPs more onerous and time consuming would be detrimental to the industry and potentially affect the health and welfare of fish.
- Veterinary medicine use in salmon is very different to that of terrestrial animals and all products within our industry are currently used as minor applications or under veterinary prescription. This is due to sporadic use, use only at certain sites or situations, small volumes used, small numbers of fish used on, or products that are regularly refined and updated. Due to these numerous reasons the registration of products for salmon is unviable to the industry.
- Additionally, all vaccines for the industry are developed locally in Tasmania through collaborative government and industry research and development. These products are bespoke and subject to regular changes to accommodate new antigens and other recipe improvements, such as dose, adjuvant volumes, adjuvant types. If full registration of these products is required it would become likely that registered products would be superseded rapidly, making the process unfeasible.
- Also, the margins on vaccines are such that the costs of registration would make vaccines uneconomical to purse for industry developers and manufacturers. The market is not currently scalable, due to regional specificities of the vaccines used in Tasmania, and the increasing cost of regulation across the board further impinges on economics for the industry.
- It should also be noted, the definition of the term 'salmonids' within the guidelines needs to be addressed. The term 'salmonids' encompasses both species 'trout' and 'salmon'. This is equivalent to using the term 'poultry' or 'ruminants' (i.e. refers to a group of animal species farmed at a different scale). Production of trout should not be considered 'major' as this species is farmed in very small quantities, therefore, the term used in the guidelines should be very specific: Atlantic Salmon.

Determining a minor use

- The change to make salmon a 'major' species would not achieve any practical or beneficial outcomes for the salmon industry, its manufacturers, suppliers, products or consumers. It instead, creates an administrative and financial burden on the industry's suppliers (some are

+61 0403 882 283
admin@salmontas.au
salmontasmania.au
83 Salamanca Place,
Battery Point, Tas. 7004

small and medium enterprises) as almost every product the industry currently uses will need to be retained under a minor use permit (MUP) because of the insufficient economic returns to register.

- Though industry would argue that all its veterinary tools would meet the concept of insufficient economic return, it is a great concern that there would be a need to repeatedly justify and furnish all the necessary information to satisfy Section 3 of the guidelines every time a MUP or renewal is required. This in turn, could deter suppliers from considering MUP's for their products, which could lead to a situation where available products, either Registered or under MUPs, are extremely limited.

Guidance key

- The guidance key is clear and understandable. It is noted the reference to 'sufficient economic return', and this is discussed in detail under Section 3 below.

Section 1 – Major crops, animals and situations

- The salmon industry opposes the proposal to list 'Salmonids' as a major species, with the reasoning of this position detailed below.

Section 2 – Limited use within a major crop, animal or non-crop situation

- The limited use matrices for veterinary products have no suggested values for salmonids, so it is difficult for an industry to assess the risks and impacts clearly for the suggested listing as a major species. It is not acceptable for such a major change to be suggested without having thought through all the aspects of the discussion paper and providing clear details to comment on, particularly in relation to the potential addition of a species group to the major list. Additionally, the production quantities and values listed in the table are low and it is suggested that these need to be re-assessed.

Section 3 – Insufficient economic return

- It is unclear from the document what quantum of economic return is considered 'sufficient'. For it to be 'sufficient', it must be a quantum above break-even or there is no driver for a commercial manufacturer to get involved in production.
- Given the costs involved in the development of, for example, the salmon industry's two main vaccines, and the historical situation where those vaccines are being continually researched and subject to regular changes to accommodate new antigens and other recipe improvements, it is estimated (according to the formula on page 10 of the consultation document) that simply to break-even would be 30% of the vaccine cost. For a manufacturer to be interested there needs to be a margin above that.
- Industry vaccines are not going to change in nature and will continue to be bespoke and low volume therefore it is considered that salmonids and its products should be retained as minor.

Salmon TASMANIA

+61 0403 882 283
admin@salmontas.au
salmontasmania.au
83 Salamanca Place,
Battery Point, Tas. 7004

Appendix A and Appendix B

- This section lists proposed changes to the major species list with no supportive or robust decision matrix. There is no rubric to guide an assessment or provide opportunity for affected parties to understand the critical data that has been used.
- For species proposed to be listed as major for the first time, the assessment needs to be more robust and transparent in its methodology and not based on subjective commentary as outlined in the consultation document. This commentary mainly focused on a volume growth over 10 years which the industry does not foresee as 'significant growth in volume' and is small in comparison to other animal proteins in Australia.
- Appendix B sets out some brief reasons ('Notes on selected commodities') for changes to species groups and those have been read and compared to assess to some extent reasoning for a change from major or minor and thus vice versa;
- It is industry's position that salmon is a minor species when compared against the other animal species:
  - The volume share of fresh protein in Australia is 38.2% chicken, 24.9% beef, 17.8% pork, 7.4% lamb and 1.2% salmon;
  - Beef produces 2,250,000mT, pork 480,000mT, lamb 621,000mT, chicken 1,256,000mT, whereas salmon produces 82,000mT, a quantum less;
- In addition, the apparent reasoning behind moving certain groups from major to minor must be considered and the decision as regards salmonids assessed in light of the indicators in those cases:
  - Pineapples and mushrooms are two groups slated for movement to minor listing;
  - Reasoning included relatively high-value low volume, few growers and limited cropping area;
  - These arguments also apply to salmon – a sector of low volume (compared to other animal proteins), just three growers and limited growing areas geographically restricted – the combined surface areas of industry pens amount to just over 100 hectares; compared to mushrooms at 132 hectares;
  - To add some other context these proposed minor species produce over 70,000mT each and mushrooms are consumed by the Australian public at a rate 50% higher than salmon (3kg per capita per year).
- In addition, it should be noted that many registered chemicals for horticulture can be used across many different cropping use-cases; and similarly, products (including vaccines) in lamb/beef/goat; and chicken/duck/turkey/other poultry. As such, the cost of registration and development can be spread across several industries, this is not the case for products used in the salmon industry. This should be accounted for in the guidelines in either the rationale or the matrix for Appendix A or B.
- Given the above comparisons, the overwhelming evidence points to salmon being a minor species.

We appreciate your consideration of our submission and if the APVMA has any queries about the above submission please contact Salmon Tasmania (contact details provided on coversheet).

Salmon TASMANIA

+61 0403 882 283
admin@salmontas.au
salmontasmania.au
83 Salamanca Place,
Battery Point, Tas. 7004

Yours sincerely,

Jessica Hyland
Environmental Specialist
Salmon Tasmania