



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



Diazinon proposed regulatory decision

Submissions received

June 2024

11 June 2024



Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO BOX 3262
Sydney NSW 2001
chemicalreview@apvma.gov.au

ABN: 25 107 507 559
ACN: 107 507 559



Re; Diazinon – Proposed Regulatory Decision

AUSVEG welcomes this opportunity to comment on the March 2024 Diazinon Proposed Regulatory Decisions (PRD). AUSVEG is the industry body for the vegetable production sector working towards meeting both the current and strategic needs of individual vegetable industries. From that perspective AUSVEG has identified potential implications for some industries from the proposed regulatory decisions in relation to the assessment outcomes highlighted in the PRD, i.e. residues and trade.

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 is the service provider for a number of grower levy-funded research and development projects that Horticulture Innovation Australia and Plant Health Australia manage.

Ensuring the results from these projects are made available to Australian vegetable, potato and onion growers is vital for the industries to remain at the forefront of global horticulture production and for local growers to operate an efficient, productive and profitable growing operation.

Firstly, regarding the lack of data on metabolites and the agency being unable to establish a residue definition for dietary risk assessment, AUSVEG understands that this concern relates to use patterns which result in finite residues. The 1993 JMPR reported various trials in which applications of diazinon, made to soil, at planting/transplanting at comparable or higher rates than approved in Australia resulted in residues below the limit of quantification (LOQ) at harvest.

From that perspective AUSVEG believes that consideration should be given to assessing data from alternative use patterns which resulted in non-detectable residues. For example, residues in cauliflower, following applications after transplanting at 25 g ai/hL, were <0.02 mg/kg, 36-

131 days after the last treatment. Further Australian trial data from three residue trials¹, previously submitted to the APVMA, residues in the harvested commodity were all <0.01 mg/kg, 14 days after the final application. A similar situation exists in bulb onions, following applications at planting of 0.6 –1.25 kg ai/ha, residues found were <0.02 mg/kg at commercial harvest.

Regarding trade, AUSVEG believes that potential impacts of retaining access to diazinon have been over stated. No vegetable commodities are listed as requiring data to be submitted in the APVMA Guideline relating to overseas trade aspects. Further Other than onions and carrots exports of vegetable commodities, Australia exports of vegetables are generally small. AUSVEG therefore believes retaining access to diazinon in these commodities would not constitute a risk to trade. Regarding carrots and onions AUSVEG believes using diazinon as an at-planting/transplanting use would result in nil detectable residues, further limiting trade risks.

Table 1 Australian vegetable exports 2023²

Commodity	Production (t)	Exported (t)	% of national production
Artichoke	450	9	2
Beans	29,118	1254	4.31
Beetroot	16167	306	1.89
Broccoli	76,316	2,215	2.90
Brussels sprouts	7,833	306	3.91
Cabbages	62,848	533	0.85
Capsicums	73,719	333	0.45
Carrots	300,715	87,847	29.21
Cauliflower	84,893	292	0.34
Celery	56,472	4,118	7.29
Cucumber	93,469	51	0.05
Eggplant	8,698	6	0.07
English Spinach/ Silverbeet/Kale	6,674	240	3.60
Garlic	2,730	0	0.00
Head lettuce	145,394	376	0.26
Leafy Asian Vegetables	29,092	0	0.00
Leafy Salad Vegetables	75,720	646	0.85
Leeks	10,127	117	1.16
Onions	255,159	36,299	14.23
Parsnips	3,593	0	0.00
Peas	25,448	6	0.02
Potatoes	1,462,975	40,672	2.78

¹ Dal Santo, P (2006). Residues of diazinon in cauliflower following four applications of diazinon insecticide to cauliflower close to harvest. Study No. diazinonAVG524.

² Australian Horticulture Statistics Handbook 2022/23

Pumpkins	118,278	2,711	2.29
Sweet corn	76,296	0	0.00
Sweet potato	91,458	987	1.08
Tomatoes	321,736	1,086	0.34
Zucchini	37,139	0	0.00

Yours sincerely,

Zarmeen Hassan
National Manager, Engagement and Extension



To:

Chemical Review
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001
Via email: chemicalreview@apvma.gov.au

Date: 19 April 2024

To whom it may concern

I write in response to a request for comments on the proposed decisions on the reconsideration of Diazinon, as published 12 March 2024.

This submission is presented on behalf of the National Working Party on Grain Protection (NWPGP) and deals with cereal commodities only.

1. 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 Support for the Decision

Based on the information provided in the proposed decision notice, industry supports:

- Changes to label uses.
- A phase-out period for those uses, no longer than 12 months.
- Changes to the MRL during the phase-out period.
- Deletion of the MRL following the phase-out period.

The above response is made on the basis of the findings in the proposed decision notice, including issues with use on the environment, residues and trade. Of note from industry is the removal of diazinon from the Codex Committee on Pesticide Residues list of chemicals and the deletion in 2023



of all CXLs. Therefore, the proposed decision from APVMA assists industry to manage market MRLs, especially relevant where markets default to Codex CXLs (which now don't exist).

Should you have any questions on this submission please do not hesitate to contact me.

Regards

A handwritten signature in black ink, appearing to read "G. McMullen", is positioned below the word "Regards".

Gerard McMullen

Chair
National Working Party on Grain Protection

[Redacted contact information]

Produced through Grains Australia Limited funding of this activity



Diazinon proposed regulatory decision

WOOLPRODUCERS
AUSTRALIA

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

6 June, 2024

Via: chemicalreview@apvma.gov.au

To whom it may concern

On behalf of WoolProducers Australia (WoolProducers), I would like to thank you for the opportunity to present this submission into the *Diazinon proposed regulatory decision*.

WoolProducers is the peak representative body for Australian woolgrowers, representing and advocating on behalf of all woolgrowers in the country, rather than just certain sectors. Our mission is to develop constructive and profitable outcomes for woolgrowers nationally.

WoolProducers represents the single largest body of woolgrowers through our fee-paying State Farm Organisation membership network and three democratically elected Independent Directors and is the only national organisation that can speak on behalf of the mainstream wool industry and represent the concerns and interests of all Australian wool producers. Our representation capacity includes the industry's commercial, superfine, broad wool and stud breeding sectors.

Woolgrowers face many challenges when it comes to maintaining animal health and welfare which is a priority for all growers. There are only a limited number of products available to producers to mitigate these challenges, and with increasing resistance and the breakdown of other chemicals the last thing industry can afford is to lose access to effective treatments. Industry must have access to as many tools in the tool kit to make our enterprises viable.

There are a number of products that have been identified in Table 2 of the *APVMA Special Gazette – Diazinon reconsideration* which are relevant to sheep and wool production, which the APVMA are considering cancelling product registration for, namely:

Approval or registration number	Name
39572	WSD Diazinon For Sheep, Cattle, Goats And Pigs
39573	WSD Fly Strike Powder To Control Flystrike And For Wound Dressing For Animals
39574	WSD Mulesing Powder Wound Dressing Following Mules Operation General Wound Dressing For Sheep, Cattle And Goats
46231	Coopers Fly Strike Powder Insecticide
51290	Eureka Gold Op Spray-On Off-Shears Sheep Lice Treatment
62353	Coopers Diazinon Sheep Blowfly Dressing And Cattle, Goat And Pig Spray
68253	Nucidol Gold Op Spray-On Off-Shears Sheep Lice Treatment

86308	Coopers Erase Gold Spray-On Off-Shears Sheep Lice Treatment
86314	Coopers Gold Spray-On Off-Shears Sheep Lice Treatment
92828	BFD Blowfly Dressing

While the actual usage of each of these products across the wool industry is unknown, there is concern that the deregistration of these products will see even less products available for woolgrowers to combat flystrike and lice.

WoolProducers urges the APVMA to assess the volume of these products that are currently in use commercially before any move to de-register their use is conducted and expedite any pending product registrations that will assist Australian woolgrowers to manage flystrike and lice in sheep flocks.

WoolProducers also acknowledge that the APVMA have conducted a thorough review of products containing diazinon based on what is referred to as 'available information', and from that the APVMA have determined that they're not satisfied that some of them meet safety and trade criteria, even if product labelling was changed or variations to product use were made.

WoolProducers notes that throughout the *APVMA Special Gazette – Diazinon reconsideration*, that there is repeated reference to decisions made on 'available information', WoolProducers would like clarification on if there is the opportunity to seek further information on diazinon to assist these deliberations or if that is it to be taken to mean that there is no further information available but the APVMA are still not satisfied that diazinon meets the required safety and trade protocols

Again, thank you for considering this submission.

Should you wish to discuss our submission further, please contact me on [REDACTED]

Yours Sincerely,



Jo Hall
CEO
WoolProducers Australia

10th June, 2024

Chemical Review Australian Pesticides and Veterinary Medicines Authority
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Re: diazinon reconsideration

On March 12th 2024, the Australian Pesticides and Veterinary Medicines Authority (APVMA) published a special gazette outlining the proposed regulatory decisions regarding the reconsideration of diazinon active constituent approvals, product registrations, and label approvals. Accompanying this gazette was an invitation to provide written submissions on the proposed course of action. In response to this invitation, Nutrien Ag Solutions commends the APVMA for its rigorous commitment to ensuring that ongoing pesticide use in Australia complies with best practices, particularly concerning trade and safety criteria. We appreciate the APVMA's diligent efforts in safeguarding public health and the environment while maintaining the availability of effective agricultural solutions.

Nutrien Ag Solutions, a major supplier of agricultural pesticides throughout Australia, is well-positioned to provide a submission to this process. In addition to operating at the retail level, Nutrien Ag Solutions is the exclusive Australian distributor of Y-Tex Corporation's range of insecticidal cattle ear tags. Specifically, in relation to the diazinon reconsideration, the following products are relevant:

Y-TEX WARRIOR INSECTICIDAL CATTLE EAR TAGS (APVMA Approval No. 51524)

NUZON 40* INSECTICIDAL CATTLE EAR TAGS (APVMA Approval No. 92417/135429)

* Currently undergoing registration approval with a proposed label issued on May 17, 2024.

Y-Tex Corporation, an American company, manufactures a range of insecticidal cattle ear tags for the control of horn fly (*Haematobia irritans irritans*) in the Americas. This range includes ear tag formulations from various insecticide modes of action, such as organophosphates, synthetic pyrethroids, and macrocyclic lactones. These products have demonstrated long-term effectiveness in controlling buffalo fly (*Haematobia irritans exigua*) infestations in cattle in Australia. Buffalo flies pose a significant threat to cattle health, welfare, and production.

Buffalo fly is prominently featured in the recent Meat & Livestock Authority's Priority list of red meat diseases, ranking as the number one disease of cattle in Australia. The report's summary on buffalo fly highlights the following concerns:

- Geographical expansion of the pest
- Increased fly challenge intensity and longer challenge periods within endemic areas
- Diminishing effectiveness of chemicals due to resistance development
- Insecticide Resistance Monitoring

The most recent survey of insecticide resistance in buffalo fly (Meat and Livestock Authority – July 2000) confirmed widespread resistance to synthetic pyrethroids in all surveyed areas and emerging resistance to organophosphate insecticides in the Northern Rivers of New South Wales. More recently, as part of our technical support and development activities in Australia, Y-Tex Corporation/Nutrien Ag Solutions have repeated this survey. The findings (currently in press) are similar to those of the 2000 survey, confirming widespread resistance development by buffalo fly to synthetic pyrethroids insecticides. While the susceptibility level to diazinon has reduced slightly compared to 2000, no significant level of insecticide resistance to this active was confirmed in the buffalo fly populations tested. Additionally, the survey investigated the development of resistance by buffalo flies to the macrocyclic lactone abamectin. Initial indications suggest emerging resistance development by buffalo flies to this mode of action in some specific regions.

Industry and government extension services advocate rotation strategies to mitigate the development of insecticide resistance by buffalo flies. The organophosphate diazinon plays a vital role in these advocated rotational strategies. The diazinon reconsideration proposes to suspend, cancel, or vary approvals or registrations for this active ingredient. According to the special gazette dated March 12, 2024, while a final decision has not yet been made, in the event of a decision to cancel, suspend, or vary, a 12-month phase-out period for the supply of relevant chemical products will be enacted. Given the importance of diazinon for the control of buffalo flies in Australia and the significance of this pest for cattle production and animal welfare, Nutrien Ag Solutions strongly requests the APVMA to consider an extension of the proposed phase-out period.

An extended phase-out period would allow for the following. Continued availability of diazinon as a crucial component of resistance management strategies, reducing the risk of resistance development to remaining available products. Sufficient time for the industry to develop and implement alternative modes of action for effective buffalo fly control. Minimizing disruptions to cattle production and ensuring animal welfare standards are maintained during the transition period. Nutrien Ag Solutions recognizes the APVMA's commitment to responsible pesticide management and urges consideration of an extended phase-out period to facilitate a smooth transition while safeguarding the interests of the Australian cattle industry. Effective control measures of buffalo fly are crucial for maintaining the well-being and productivity of the Australian cattle industry.

During a stakeholder meeting held on March 18, 2024, between the APVMA and representatives from Y-Tex Corporation and Nutrien Ag Solutions, the implications of the

diazinon reconsideration were extensively discussed. The major finding from the review relates to residue concerns. According to the APVMA, a residue definition for diazinon cannot be established for risk assessment or compliance with the Maximum Residue Limits (MRLs) for plant and animal commodities treated with diazinon chemical products based on the available information. Specifically, this issue pertains to two impurities of toxicological concern: O,O,O',O'-tetraethyl dithiopyrophosphate (S,S-TEPP) and O,O,O',O'-tetraethyl thiopyrophosphate (O,S-TEPP). The crux of the matter is that the available information is insufficient to determine whether the active constituents meet the specifications outlined in the APVMA's Active Constituents Standard 2022 and the FAO specifications. Additionally, there are concerns regarding the potential presence of unacceptable levels of impurities of toxicological concern in the active constituent. Y-TeX Corporation and Nutrien Ag Solutions acknowledge the APVMA's concerns regarding residues and impurities.

At this stakeholder meeting, it was established that the APVMA is receptive to the generation of data for diazinon and its impurities of toxicological concern, which would support compliance with the APVMA's Active Constituents Standard 2022 and the FAO specifications. However, studies in this area have not been initiated yet. Conducting the required studies will involve a considerable timeframe. Initially, an analytical method must be developed to accurately measure the impurities. Subsequently, a target animal residue study must be commenced, which includes the requirement to develop a method for confirming the stability of the impurities in stored tissues for residue analysis. The APVMA would acknowledge that even if work were to commence immediately to undertake these required studies, the findings would not be available within the intended phase-out period proposed in the reconsideration. Generating comprehensive data to address the residue and impurity concerns should justify an extension to the proposed phase-out timeline.

Y-TeX Corporation/Nutrien Ag Solutions acknowledges the APVMA's findings regarding residues and impurities of toxicological concern. We respectfully request the APVMA to consider granting an extended phase-out period to allow for the generation of the required residue data and comprehensive studies. Y-TeX Corporation is actively investigating the requirements and collaborating with industry partners to undertake these necessary studies. Initial discussions have been held with another supplier of diazinon-based products to initiate collaborative efforts in conducting these studies. An extended phase-out period would not only facilitate the development of alternative modes of action for buffalo fly control but also reduce the risk of resistance development against the remaining available products for this pest, ensuring long-term sustainable solutions.

Maintaining robust and proactive control measures for not only buffalo flies but all diseases is paramount to safeguarding the vitality, economic viability and well-being of Australia's cattle industry for years to come.

SUBMISSION

11 June 2024

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

Via email: chemicalreview@apvma.gov.au

Dear Sir/Madam

Re: Diazinon proposed regulatory decision

Cattle Australia (CA) is the peak industry organisation representing Australia’s grass-fed cattle producers. CA provides clear leadership and direction for the grassfed beef cattle industry by developing and driving contemporary policy, guiding research, development and adoption, and marketing investment for the sector, and advocating on matters important to the Australian cattle industry.

CA welcomes the opportunity to provide comment on the Australian Pesticides and Veterinary Medicines Authority (APVMA) recently published proposed regulatory decision for the reconsideration of diazinon in the APVMA Special Gazette, 12 March 2024 (the Annex). We recognise that the APVMA is proposing to make regulatory decisions in relation to the reconsideration of diazinon active constituent approvals, product registrations, and label approvals being conducted under Part 2, Division 4 of the Agricultural and Veterinary Chemicals Code scheduled to the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code).

There are a number of products that are listed in the Annex table 2: Active constituent approval(s), product registration(s) and associated label approval(s) placed under reconsideration, that the APVMA is proposing to cancel, that if cancelled will pose significant risk to the Australian cattle industry and Australia’s biosecurity integrity. These products are namely:

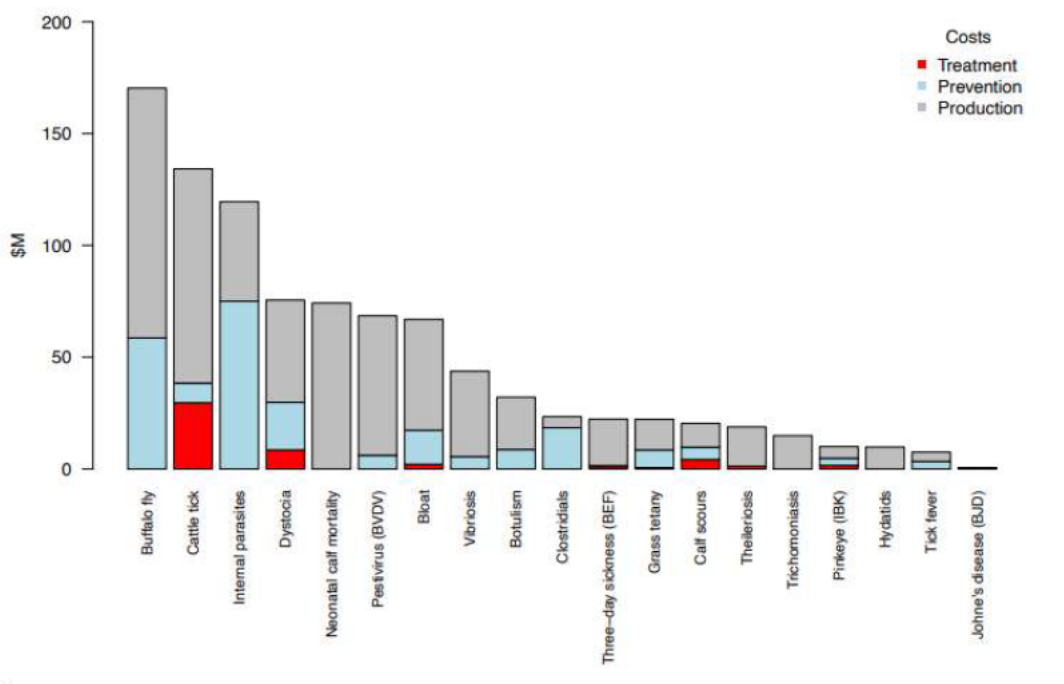
Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product
Product	39572	WSD Diazinon For Sheep, Cattle, Goats And Pigs	WSD Agribusiness Pty Ltd	39572/0614
Product	39573	WSD Fly Strike Powder To Control Flystrike And For Wound Dressing For Animals	WSD Agribusiness Pty Ltd	39573/0614
Product	39574	WSD Mulesing Powder Wound Dressing Following Mules Operation General Wound Dressing For Sheep, Cattle And Goats	WSD Agribusiness Pty Ltd	39574/0614
Product	46406	Y-Tex Optimizer Insecticidal Cattle Ear Tags	Nutrien Ag Solutions Limited	46406/01, 46406/0503, 46406/5283, 46406/111798, 46406/119795
Product	51524	Y-Tex Warrior Insecticidal Cattle Ear Tags	Nutrien Ag Solutions	51524/0202, 51524/0303, 51524/0999, 51524/50285,

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Type	Approval or registration number	Name	Holder	Label approval number(s) associated with the product
			Limited	51524/106701, 51524/111799, 51524/119797
Product	53910	Patriot Insecticide Ear Tag For Cattle	Elanco Australasia Pty Ltd	53910/0507, 53910/0702, 53910/0801, 53910/130969
Product	60662	Co-Ral Plus Insecticide Cattle Ear Tag	Elanco Australasia Pty Ltd	60662/0710, 60662/130564
Product	62353	Coopers Diazinon Sheep Blowfly Dressing And Cattle, Goat And Pig Spray	Intervet Australia Pty Ltd	62353/0614

CA would like to draw attention to the use of ear tags and their ability to control insect bites in cattle. The products Y-Tex Optimizer Insecticidal Cattle Ear Tags, Y-Tex Warrior Insecticidal Cattle Ear Tags, Patriot Insecticide Ear Tag for Cattle, Co-Ral Plus Insecticide Cattle Ear Tag, which are used extensively in the northern cattle industry, play a critical role in northern Australian animal welfare and biosecurity management. Meat and Livestock Australia have conducted research in 2022 that assesses the financial impact of endemic diseases on farm productivity and highlights the importance of insect bite management. The report¹ shows that two of the highest cost endemic diseases of cattle are caused by external parasites (flies and ticks). The total annual cost of buffalo fly in cattle across Australia is estimated at \$170.3M. The report also includes the following graph which helps put these costs in context when comparing the annual economic cost of the priority diseases for cattle in Australia:

Cattle:



¹ <https://www.mla.com.au/research-and-development/reports/2023/B.AHE.0327-priority-list-of-endemic-diseases-for-the-red-meat-industry--2022-update/>, sourced 2/4/24.

CA recognises that the APVMA has made an assessment of Ear tag, back rubber, rubbing post, high and low volume spray containing diazinon and that these products have been determined that veterinary uses is not supported based on the available information due to residue and trade risks. We acknowledge that this assessment has been made in light of some international diazinon MRLs for animal commodities having been recently lowered or withdrawn. As noted in the technical report that supports the Annex:

“Considering the available residues data, it is therefore not possible to establish a suitable ESI, for all spray, backrubber, wound dressing and ear tag uses for cattle, as it is unknown when residues would decline to be less than the LOQ. The risk to international trade of cattle meat and offal is therefore considered to be undue given recent changes in international MRLs for diazinon²”

CA acknowledges that the APVMA have done a thorough investigation of these products based on available information and would urge the APVMA to seek additional data on the MRL levels that result from ear tag usage. Ear tag products play a crucial role in fly control, particularly in preventing resistance through rotation strategies. Further investigation is warranted to inform the introduction of an export slaughter interval for ear tag use, given their topical application and minimal systemic absorption, and is a reasonable approach to address regulatory concerns without sacrificing efficacy. CA contends that the ear tags actively manage insect bites that if present restrict trade to our live export markets.

The significance of having a variety of tools to combat fly bites cannot be overstated. Biting flies not only cause discomfort and stress to cattle, pose a significant biosecurity risk and also result in economic losses due to reduced productivity and potential health issues. Therefore, having access to multiple products and strategies is essential for effective pest management.

Rotation of products is a vital component of any pest management program. By rotating products, we can mitigate the development of resistance in fly populations, thus ensuring the continued efficacy of our control measures. This principle holds true not only for routine fly control but also in the event of a biosecurity incursion, where rapid and varied responses are necessary to contain and eliminate threats. Industry has invested heavily in maintaining freedom from lumpy skin disease (LSD) that is currently present in Indonesia. Since the NABS Masterclass in March 2023, approximately 70 skin samples have been received by state and territory governments, as reported in the NABSNet August newsletter. None of the sample’s pathology were consistent with what would be expected in LSD. The most common cause for the lesions was pathology related to insect bite hypersensitivity.³

Unfortunately, the cattle industry in Australia faces significant challenges due to limited product availability to combat biting flies and insects. Our market size limits our ability to influence label changes or attract new products, exacerbating the issue. Without access to the full range of products available, we risk the development of resistance in fly populations, undermining our efforts to control these pests effectively.

However, the current market for insecticidal ear tags is narrow, with only Nutrien and Elanco serving as suppliers. Eliminating these products from the Australian landscape would leave cattle producers without a viable rotation strategy, further exacerbating the issue of resistance.

Furthermore, the absence of new molecules under review compounds our predicament. With limited options for innovation in insecticidal products, we must prioritize the preservation and judicious use of existing tools to maximize their effectiveness and longevity. Should the APVMA decide to proceed with its decision to cancel these products, it is critical that industry is provided the maximum transition time.

² [Diazinon Review Technical Report \(apvma.gov.au\)](https://www.apvma.gov.au), p41

³ DAFF External Update FMD LSD 29052024

In conclusion, it is imperative that we preserve and retain accessibility of diverse tools for combatting fly bites in the cattle industry. By maintaining a robust arsenal of products, implementing rotation strategies, and exploring innovative solutions, we can safeguard the welfare of our livestock, mitigate economic losses, and sustain the long-term viability of our industry.

Thank you for considering these important points. I look forward to further dialogue and collaboration on this crucial issue. If there are any queries about this submission, please do not hesitate to contact our office on [REDACTED]

Yours sincerely

A handwritten signature in cursive script, appearing to read 'Chris Parker'.

Dr Chris Parker
Chief Executive Officer



Elanco Australasia Pty Ltd

ABN 64 076 745 198



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Chemical Review
APVMA
GPO Box 3262
Sydney NSW 2001

By email

11 June 2024

APVMA Reconsideration of Diazinon

Submission on proposed decisions

In relation to:

Patriot Insecticide Ear Tag for Cattle (APVMA 53910)

Co-Ral Plus Insecticide Cattle Ear Tag (APVMA 60662)

Dear Sir/Madam,

Elanco Australasia is the registration holder for the two products named above. On 12 March 2024, APVMA published its proposed decisions in relation to the chemical reconsideration of diazinon. These proposed decisions include the cancellation of the registration for these two products, on the basis that a satisfactory definition of a marker residue for diazinon can not be established from existing data. Therefore, the proposed decision indicates that the existing Australian MRLs, and withholding periods for the products, can not be supported.

Elanco does not challenge APVMA's assessment of the existing data.

However, we request that APVMA consider a longer period for supply and use of these ear tag products after a final decision is made on the reconsideration. These tags are crucial for the control of buffalo fly in cattle in northern Australia, and a longer phase-out period will assist producers in managing the move to alternative control methods.

Additional detail

Patriot Insecticide Ear Tag for Cattle (APVMA 53910) contains diazinon as its active constituent, and Co-Ral Plus Insecticide Ear Tag for Cattle (APVMA 6002) contains diazinon and coumaphos. Both are indicated for control of susceptible buffalo fly for up to 4 months in beef and dairy cattle, including synthetic pyrethroid resistant populations.

Control of buffalo fly is critical for the management of cattle in northern Australia. A 2022 report from Meat and Livestock Australia identified buffalo fly as the most costly endemic disease in Australian cattle, costing the industry more than \$170 million per year¹. Infestation leads to reduced weight gain in beef cattle, and reduced milk output in dairy cattle. Chronic infestations lead to skin sores and hide damage, with the fly acting as a vector for the *Stephanofilaria* spp. nematode, which in turn causes more severe skin lesions. With climate change, buffalo fly is expanding geographically, with more intense and longer challenge periods in endemic areas.

Insecticidal ear tags are a primary form of control, as these cattle are extensively grazed with limited management interventions. Producers currently have three chemical groups that can be used for control of buffalo fly in ear tag form:

Organophosphates (OP): Diazinon (Patriot, Co-Ral Plus, Y-TeX Warrior (APVMA 51524) ear tags)

Synthetic pyrethroids (SP): Beta-cyfluthrin (Cylence Ultra ear tag, APVMA 60621)

Macrocyclic lactones (ML): Abamectin (Y-TeX Agressor ear tag, APVMA 62199)

Resistance in buffalo fly to these chemicals, especially the SP group, is a known and serious issue. As such, rotation between chemical groups is recommended as best practice². Currently, industry recommendations are to rotate insecticidal ear tag chemical groups on an annual basis in a three year rotation incorporating synthetic pyrethroid, organophosphate and macrocyclic lactone tags. If a spray, pour-on or dip treatment is required in the same fly season then it is recommended to use a different chemical group to that used in the insecticidal tags for that year.

Removing one chemical group (organophosphates) from the available options will seriously impact overall control, given the existing serious resistance to SP ear tags. This will worsen the already significant negative animal welfare impacts for cattle in northern Australia, and negative economic impacts for cattle producers.

We request that APVMA consider these impacts when determining speed of implementation of any decision made in this chemical reconsideration. It is worth noting that it is 30 years since the nomination of diazinon for reconsideration, and 28 years since the reconsideration was commenced. APVMA's reconsideration has not found evidence of harm for animals, people, or the environment through the use of diazinon in registered products – rather that the existing toxicology data does not meet contemporary standards for definition of MRLs and withholding periods. In the absence of such evidence of harm, we request that APVMA consider the negative impacts for animals in its speed of implementation of decisions from the reconsideration.

Proposal

It is Elanco's understanding that if a final decision is made to cancel the registration of Patriot and Co-Ral Plus, APVMA's standard practice will be to consider a "deemed Permit" to be in

¹ Shephard *et al.* (2022) B.AHE.0327: Priority list of endemic diseases for the red meat industry — 2022 update. MLA.

² <https://flyboss.com.au/manage-pesticide-resistance/>, 4 Jun 2024.

place to allow the supply and use of the affected products for 12 months from the date of cancellation (Agvet Code Section 45B).

If a cancellation decision is made, **Elanco requests that APVMA consider issuing a separate Item 23 Permit to Elanco allowing supply and use of Patriot and Co-Ral Plus for three years from the date of cancellation.**

A longer implementation period will give cattle producers and product registrants time to redefine best practice for management of buffalo fly, and potentially seek alternative chemical options.

The author signing below can be contacted on behalf of Elanco Australasia in relation to this submission.

Yours sincerely,

Robert Pottie,
Director of Regulatory Affairs ANZ.

[Redacted signature]



Xavier Martin
President

Ref: 24890C

11 June 2024

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

Via email: chemicalreview@apvma.gov.au

To Whom It May Concern,

RE: Submission to Diazinon proposed regulatory decision

NSW Farmers welcomes the opportunity to provide a submission to the Australian Pesticides and Veterinary Medicines Authority's (APVMA) public consultation on the proposed regulatory decision for the reconsideration of diazinon, published in the APVMA [Special Gazette, 12 March 2024 – Diazinon reconsideration](#).

Diazinon continues to be an important veterinary chemical for livestock management in New South Wales, particularly for sheep and wool producers. There are a number of product registrations identified in Table 2 of the *APVMA Special Gazette – Diazinon reconsideration* which are proposed to be cancelled that remain important tools used for the humane management of wounds, fly strike and lice for sheep. Additionally, insecticide ear tag products containing diazinon remain important for the cattle industry, for example to control buffalo flies. As such, NSW Farmers provides strong support for the retention of the registration of products currently approved for these purposes.

Animal health and welfare is a priority for all livestock producers, and access to as many products as possible is important to ensure that the industry can uphold Australia's reputation for producing high quality clean, green and safe food. Sheep and wool producers have access to a limited number of products to combat flystrike and lice and do not want to lose effective and humane diazinon treatments that are currently available. There are also considerable concerns about the impacts to the industry should diazinon not be available with increasing resistance issues in these insect populations. Similarly, insecticide tags containing diazinon remain an important tool for cattle producers, used in integrated pest management strategies with other chemicals to manage buffalo flies and mitigate resistance issues in fly populations, particularly in parts of northern New South Wales.

For example, it is estimated that flystrike alone costs the Australia sheep industry approximately \$323 million per annum in prevention, treatment and production costs.³ Causing 10-20 per cent mortality rate in fly struck sheep, chemical use is often necessary to both treat and prevent. However, resistance to the most commonly used, preventative chemicals, cyromazine and dicyclanil, has emerged with a recent 2020 study conducted by

³ Shephard, R.; Webb Ware, J.; Bloomfield, B.; Nietha, G. (2022). Priority list of endemic diseases for the red meat industry - 2022 update in: Final Report B.AHE.0327. Prepared for Meat & Livestock Australia.

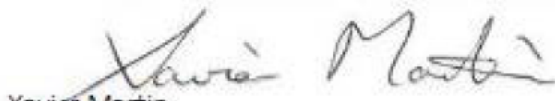
the NSW Department of Primary Industries and Australian Wool Innovation Limited finding higher rates of resistance in New South Wales compared to other states.²

NSW Farmers acknowledges that the APVMA's review has determined that a residue definition for diazinon cannot be established for the purposes of risk assessment or compliance with the MRLs for animal commodities treated with diazinon chemical products based on the information available. However, given the importance of having as many products to combat insect pests and maintain livestock health, NSW Farmers recommends that further consideration into options to maintain registration for diazinon products used for these purposes be undertaken by the APVMA.

NSW Farmers is also not aware of any diazinon chemical residue detection issues caused by the current uses of the product. For example, the National Residue Survey results for diazinon residue in 2022-23 and 2021-22 reported zero detections in sheep above the Maximum Residue Limit (MRL) of 0.7 mg/kg or between the Limit of Reporting (0.02 mg/kg) and MRL.³

Used safely and responsibly per the product label directions, NSW Farmers reiterates the importance of the availability of diazinon products for livestock producers in New South Wales. Should you wish to discuss this submission further, please contact [REDACTED]

Yours sincerely,



Xavier Martin
President
NSW Farmers

About NSW Farmers

NSW Farmers is Australia's largest state farming organisation, representing the interests of its farmer members in the state. We are Australia's only state-based farming organisation that represents farmers across all agricultural commodities. We also speak up on issues that matter to farmers, whether it's the environment, biosecurity, water, animal welfare, economics, trade, workforce or rural and regional affairs.

² Australia Wool Innovation Limited, (2020). Blowfly Insecticide Resistance – Research results and advice for woolgrowers. Accessed: <https://www.wool.com/globalassets/wool/sheep/research-publications/welfare/non-invasive-management-practices/insecticide-resistance-study-bfb-dec-2020.pdf>

³ Department of Agriculture, Fisheries and Forestry. National Residue Survey - Sheep residue testing annual datasets 2021-22. Accessed: <https://www.agriculture.gov.au/sites/default/files/documents/sheep-residue-testing-annual-datasets-2021-22.pdf>. Department of Agriculture, Fisheries and Forestry. National Residue Survey - Sheep residue testing annual datasets 2022-23. Accessed: <https://www.agriculture.gov.au/sites/default/files/documents/sheep-2022-23.pdf>.

Thanks for your email.

We agreed the works on the reconsideration of diazinon and we believe that APVMA will make a scientifically reasonable decisions on diazinon's future after reconsideration. Please find attached public submission coversheet as per your request.

Should you have any queries, please do not hesitate to contact us.

Thanks & Best Regards,

Cherry Mak



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