To: Ministry for Primary Industries
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**Submission on: The regulation of inhibitors used in agriculture**

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**Submitter:**

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# Submission on: The regulation of inhibitors used in Agriculture

## Introduction

Agcarm welcomes the opportunity to comment on the proposals outlined in 'The regulation of inhibitors used in agriculture' discussion paper. Overall, we agree that inhibitors require a higher level of legislative oversight by the government.

Agcarm highlights the offer of one of our members to share with ACVM the most comprehensive data set available for an inhibitor to assist in developing the details for this proposed policy.

Our specific comments are provided as follows.

## Questions on the problem definition

**1. Do you agree with this characterisation of the problem? If not, why not?**
Yes, we are supportive of the problem definition.

**2. In your view, what are the problems or advantages with the current regulatory settings in respect to inhibitors?**
The current settings allow for easy and low cost market entry.

However, there are multiple risks with the current settings, for example, no reassurance to end users, potential residue, trade and environmental issues, along with allowing products to be used that are not effective.

**3. How significant are these problems?**
Highly significant.

The current regime exposes New Zealand and our food supply at risk to unknown residue and potential contamination. This in turn could have a major negative effect on trade, waterways and the general environment.

**4. What evidence do we need to examine to inform further analysis of the problems? Is this evidence readily available?**
No – the problems are clearly visible and well documented.

***Questions on definition of an inhibitor***
*Definitions can be outcomes based or more prescriptive.*

*An example of an outcomes based definition is:*

> *Inhibitor – Any substance, mixture of substances, or biological compound, used or intended for use on plants or animals, or to be applied to the place, feed or water on or in which there are plants or animals, for the purposes of –*
> *Mitigating environmental, sustainability, and/or climate change impacts.*

*Whereas an example of a prescriptive definition is:*

> *Inhibitor – Any substance, mixture of substances, or biological compound, used or intended for use on plants or animals, or to be applied to the place, feed, or water on or in which plants or animals exist, for the purposes of –*
> *Impacting the processes of nitrification, denitrification, ammonia volatilisation, urease production, or methanogenesis.*

**5. Which of the definitions above do you prefer, and why?**
Some members within Agcarm indicated support for the prescriptive definition, while others are more in favour of the outcomes based definition. This has been explored further with Agcarm members.

As an outcome we submit more in favour of a broad outcome based definition of inhibitors, as proposed in the consultation paper. Some fine tuning of the definition is required, to assist in capturing targeted products in this category, and to also future proof the regulation if products with new functions are developed in the future.

As with wider industry feedback, Agcarm would expect the regulations to further categorise inhibitors and perhaps even exclude some from the requirements of registration. By capturing this in the regulations rather than the Act it allows for more flexibility in the future.

We also submit that there may be cases where exemptions are required, for example products that offer crops with frost protection. Hence, we submit that an exemption option is retained in any new legislation.

**6. Is 'inhibitor' the best term to use to describe these types of substances? Why or why not – and if not, what alternative do you suggest?**
Yes – this will keep them in a separate category, such as crop protection and animal medicines are currently classified.

**7. Are you aware of any definition used internationally that could be relevant to New Zealand?**
Yes – but, we prefer industry and government to develop an agreed New Zealand specific definition.

**8. Should the definition for an inhibitor be outcomes based? Why or why not?**
See 5 above.

**9. What, in your view, should be in scope of the inhibitor definition? Are there any substances, mixture of substances, or biological compounds that should be specifically excluded?**
It is possible that some products may fall outside the definition. This could be covered by offering an 'exemption application' clause in the legislation.

**10. How would you define an inhibitor?**
See comments in section 5.

**11. What else should be considered in relation to how an inhibitor should be defined?**

***Questions on transitional period***
*Should a transitional period be required, how long should the transitional period last for those products already available? For example, the Agricultural Compounds and Veterinary Medicines (Transitional Provisions) Regulations 2002 provided for a transitional period of two years. This may also be appropriate for inhibitors.*
*We seek your views on an appropriate transitional period:*

**12. Do you agree that a transitional period for products exempt from registration is unlikely to be required? Why or why not?**
As with other industry groups Agcarm supports a transitional period, but only to cover products currently on the market.

In addition, this should be a managed process to ensure no undue risk, where:

- Products on the market the day the Order of Council is completed could apply
- Manufacturers/ suppliers would apply for their products to be eligible
- Permission to remain on the market would be granted based on an assessment of the claims and potential risks (for products applied to animals this assessment may be more stringent)

- We support up to a five year transitional period if it is managed in this way

**13. Are you supportive of a transitional period for products requiring registration? Why or why not?**
See 12 above

**14. Are you supportive of the transitional period covering products that are already in the market, only? If not, why not? What alternative would you propose?**
See 12 above

**15. If you are a producer and or exporter, do you consider you are capable of managing any risks to trade from inhibitors in the interim, during the transitional period?**
Not applicable

**16. Is two years an appropriate period of time for a transitional period? Why or why not? Please provide rationale for an alternative period of time.**
No – 5 years is preferred

This will provide more time to collate the required data and evolve internal systems that will be needed to make sure that the product meets the new legislative requirements.

**17. Do you currently import, manufacture, or sell inhibitors? What would the impact of a two year transitional period be on your business? How much product would be affected?**
No applicable

**18. Would you like to suggest another option to a transitional period? If so, please provide a description of that option, reasons for supporting that option and its advantages and disadvantages.**
Not applicable

**Questions on criteria**
19. Do you agree with the proposed criteria? Why or why not?

**20. Would you propose any other criteria not covered?**
No

**Questions on the proposed options**
**21. Which of the proposed options do you prefer and why? If you have an alternative option that has not been considered above, please describe this option, including its rationale, and how it would perform relative to the five criteria.**
Of the three options presented, Agcarm do not see any alternative but **Option 3** (where legal obligations would apply), due to the potential trade risks related to residues.

The issue here will be drafting the legislation so it protects trade, human health and the environment without hampering innovation. Every effort will need to be made to ensure that we don't have a repeat of the issues that we have with the HSNO Act where the rules (or particular interpretations of them) make it really difficult to trial and register new products which could replace older chemistry which may have higher environmental and health risks.

It would be a good idea for those drafting the new legislation to have a think about how similar existing legislation is or is not working first. Much depends on how exactly inhibitors are firstly defined, and secondly, regulated, and we don't support regulating them exactly the same way as pesticides.

**22. Do you currently import, manufacture, or sell inhibitors? Do you consider that you are sufficiently managing risks to trade, plant and animal health, and food safety? Please explain and provide evidence to support your answer.**
Not applicable

**23. Under option 3, would you support registration of some or all inhibitors, or some or all inhibitors being exempt from registration? Please advise your rationale for your choice.**
We support the ability to exempt relative products from registration. This may include some vaccines, or crop protection products that fall outside the true definition of an inhibitor. These products may already be registered with the EPA and/or ACVM team, and would not require further registration as an inhibitor.

**24. Do you currently import, manufacture, or sell inhibitors? Please describe what impact implementing option 2 would have on your business or the market you operate in. How much product would be affected? What do you estimate would be the cost?**
Not applicable

**25. Do you currently import, manufacture, or sell inhibitors? What would the impact of implementing option 3 but exempting inhibitors from registration have on your business? How much product would be affected? What do you estimate would be the cost?**
Not applicable

**26. Do you currently import, manufacture, or sell inhibitors? What would the impact of implementing option 3 and requiring registration have on your business? How much product would be affected? What do you estimate would be the cost?**
Not applicable

**Questions on efficacy**
Exact data requirements are outside of the scope of this discussion document. However, your feedback is sought on whether:

## For Questions 17 to 32 and General Comments

A few points made in the consultation paper are confusing. The question of whether inhibitors should be registered is listed out of scope of this consultation (p. 2):

**What is out of scope?**

- exactly how inhibitors would be managed if regulated under legislation, such as how they would be categorised, whether they would be registered, or specific details on guidance and guidelines on what manufacturers need to supply to support the registration of inhibitors under the ACVM Act;

We submit that the point highlighted is one of the core questions within this consultation.

In some instances, the consultation paper suggests that inhibitors could be brought within the scope of the ACVM Act but exempted from registration (see questions 23, 25 and 26, information note on p. 9).

Perhaps ACVM should clarify what obligations apply in such a situation and how they would address the criteria for assessing the proposed amendments outlined in Section 5. This is somewhat at odds with the rest of the consultation paper, which seems to assume that bringing inhibitors within the scope of the Act is synonymous with requiring registration. This seems to be the assumption underlying assessment of options against criteria in Section 6 (i.e. that all risks would be assessed by ACVM, MRLs would be set – this can only be the case when inhibitors need to be registered).

**Residue Management**
In addition, the management of residues (if regulated) is stated to be out of scope (p. 2), whereas elsewhere it seems MRLs are assumed to apply to inhibitors if brought within the scope of the Act (as this is assumed to be synonymous with registration) – see Section 6.2.

**Regulation – keeping separate from Pesticides**
The consultation paper seems to assume that if inhibitors are regulated, they would be regulated exactly the same as pesticides. At this early stage, we would like to urge MPI to be open to regulation options within the ACVM, which would differ from how pesticides are regulated.

Inhibitors would become an agricultural compound but should be kept separate from pesticides, in terms of the definition as well as the requirements for registration. Inhibitors are not widely regulated globally and do not have global data packages, the most expensive component of regulatory submissions. New Zealand would unlikely present a business opportunity to support generating such a comprehensive data set. A cow feeding study alone, which is required for animal transfer evaluation, presents a cost of several hundred thousand USD, up to a million USD. The data requirements for inhibitors should be flexible and realistic (e.g. only overseas data for Magnitude of Residue trials if available, argument or simplified / alternative data for animal transfer and metabolism).

ACVM should have realistic expectations about what is or can be available for inhibitors. A global dossier to the same standards as for a novel pesticide is ~~not~~ highly unlikely.

**Trade Risk**
The trade risk evaluation for pesticides cannot be easily extended to inhibitors. How will ACVM determine the risk acceptable when most destination countries do not have any MRLs or other regulatory acceptable levels established for inhibitors? Would the residues have to be below LOQ? Or LOD? Would the assumption be that the New Zealand MRL would be honoured in destination markets in the lack of domestic standards? What management options would manufactures have to facilitate trade if the destination country does not have any process in place to establish acceptable levels?

How will ACVM evaluate animal transfer when no cow feeding study is available? In our opinion MRLs should not automatically apply to inhibitors. Perhaps a different type of a regulatory acceptable level can be considered. New Zealand is leading a CODEX working group on the Proposed Draft Guidelines '*For Risk Analysis of Chemicals Inadvertently Present in Food at Low Levels*'. Similar risk assessment principles could be applied to inhibitors if brought within the scope of the ACVM Act.

**Case Study – Offer of Support**
An Agcarm member has indicated that they would be in a position to share the relevant components with ACVM to be used as a case study to help formulate the details of the policy. This is on the condition that the information would be treated as confidential and the provision of it for the purposes of a case study would not compromise their eligibility for data protection should they make an application in the future.

## 3. About Agcarm
Agcarm is the peak New Zealand industry association of companies which manufacture, distribute and sell crop protection and animal health products. Our mission is to protect and enhance the health of crops, animals and the environment - through innovation and responsible use of quality products and services.

For over 70 years, Agcarm has taken a lead role in managing issues of importance to the crop protection and animal medicines industries. This involves engaging with politicians, regulators and stakeholders to ensure that decision-makers take account of industry's views. It also ensures that industry aligns itself with best practice in the management of pests and disease.

Our members research the safest and best methods to do this. In the crop protection industry, our manufacturers support the use of Integrated Pest Management (using all means available to tackle pests

and disease). They research all means of control, including biologicals, to ensure the best and most sustainable result for farmers and growers.

Membership to Agcarm is voluntary, with all applicants requiring Board endorsement before being accepted. Agcarm backs this by ensuring all members comply with a Code of Conduct.

This Code certifies that Agcarm members meet industry standards. Compliance with it is a condition of membership - with companies required to meet a number of obligations. This includes complying with relevant legislation, participating in environmental stewardship programmes, acting ethically in product promotion and in accordance with the best interests of industry.

Protecting the environment is integral to this, with support and participation of the rural recycling programme Agrecovery being compulsory for members. Companies must also ensure that their products meet an appropriate standard, all people involved with industry products are appropriately trained, and that they are supportive of ensuring environmental sustainability.

In promoting a healthy environment, Agcarm is involved in a number of other stewardship campaigns, within the crop protection and the animal medicines industries.

Bee health is high on the association’s agenda with regular campaigning to protect the wellbeing of New Zealand’s bee population, and ensuring that products are used responsibly. The ‘Bee Responsible’ awareness campaigns were produced in conjunction with the Rural Contractors and Agricultural Aviators associations to raise awareness of the importance of protecting bees and providing guidance.

Preventing resistance management in animals and plants is another priority for the association and its members. As part of this, Agcarm leads and supports programmes that prolong the effectiveness of crop protection and animal health products liable to encounter resistance problems, and limit losses should resistance appear.

This includes an integral role in the Wormwise Trust - providing expert advice to farmers on managing worms on farms (anthelmintic resistance) as well as antimicrobial resistance. Agcarm contributed to New Zealand’s Antimicrobial Resistance Plan which was submitted to the World Health Organisation in May 2017.

The association’s ultimate purpose is to ensure that New Zealand continues to lead the world in producing safe, healthy and sustainable food by using the best and safest technology. By dealing with an Agcarm member you too will be part of this worthy goal. So, next time you are considering a purchase of a pesticide or animal medicine, ask if the company is an Agcarm member and if they are you can be assured that you are dealing with knowledgeable staff and a quality product.

# APPENDIX 1: Agcarm Membership

## Agcarm Membership

Agcarm represents around 90 percent of the crop protection, animal medicines and rural retailers industries within New Zealand. Our companies are both local and globally linked, producing products that enable our farmers and growers to supply high-quality food and fibre into domestic and international markets, along with keeping our animals and pets healthy.

**Animal Health Manufacturers**

- Bayer Animal Health
- Boehringer Ingleheim
- Ceva
- Donaghys
- Ravensdown
- Elanco Animal Health
- MSD Animal Health
- Zoetis NZ
- Troy Animal Medicines

**Crop Protection Manufacturers**

- ADAMA New Zealand
- AgriNova NZ Ltd (trading as Grochem)
- BASF New Zealand
- Bayer CropScience
- Donaghys
- Corteva
- FMC
- UPL
- Key Industries
- Ravensdown
- Nufarm
- Syngenta Crop Protection
- Lonza
- Kiwicare

**Distributors**

- Ashburton Trading Society
- Farmlands Co-operative
- Horticentre
- ICD Group
- New Zealand Farm Source
- PGG Wrightson Ltd
- Venture Exports
- Hodder and Turner

**Corporate Associates**

- AgriMedia
- Argenta
- Eurofins Agrosciences Services
- Medicines New Zealand
- Peracto New Zealand
- Philstic Labels
- Rural Contractors

- Sumitomo Chemical
- Rainbow chemicals

**Individual Associates**

- Hill Laboratories
- RxVet Limited
- Mantissa Corporation
- Agworld
- Ag Services
- NZ Apple and Pears
- Market Access Solutionz
- Renovo Technologies
- NZ Sports Turf Institute
- Molloy Agricultural Spraying
- Intuit Animal Health Consultants
- Zespri
- HortNZ
- Tracta
- IPPC
- BNS Agchem
- Redcap solutions
- De Groot
- Ranfurly Orchard Services
- NZKGI
- BioGro
- FieldTek
- On Regulatory
- De Sangosse
- Educhem
- Ranui Field Research