Feedback

on Behalf of
The Fertiliser Association of New Zealand

on

The regulation of inhibitors used in agriculture

MPI Discussion Paper No: 2020/01

To

Ministry for Primary Industries
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Introduction

1. The Fertiliser Association of New Zealand (‘‘the Association’), is an industry association funded by member companies, to address issues of common public good. Member companies include Ballance Agri-Nutrients Ltd and Ravensdown Ltd. Both these companies are farmer co-operatives with some 45,000 farmer shareholders. Between them these companies supply over 98% of all fertiliser used in New Zealand. The cooperative base of the Association members means the industry is not driven by product sales to its farmer shareholders, but by delivering best value to its farmer shareholders.
2. The Association member companies have pan sector interests and responsibility, currently with the largest team of on-farm advisers of any of the primary sector groups. The fertiliser industry products, nutrient management advice and resources are central to environmental issues associated with nutrient loss and greenhouse gas emissions from farm systems.
3. The Association member companies have invested significantly in products, systems and procedures which support responsible nutrient management to support a viable primary industry within environmental limits.
4. The Association takes a particular interest in regional and national policy, regulation and guidelines which support sustainable management of natural and physical resources, and seeks that any regulation that may address the use of fertilisers and related products is appropriate and necessary to achieve its intent for the benefit of all New Zealand.

Context and background

5. The issues described in the consultation documents are, ‘in a nut shell’, seeking the best way to ensure the potentially very significant environmental benefits of “inhibitor” products can be realised in primary production in New Zealand, while at the same time meeting national and international market standards for food safety, trade, environmental wellbeing and plant and animal health.
6. The key issues arise with new products or new applications of existing products which have the potential to provide for significant environmental benefits, but are not covered under the Agricultural Compounds and Veterinary Medicines Act

SUBMISSION- IN- FULL

Questions on problem definition
Q1. Do you agree with this characterisation of the problem? If not, why not?
Q2. In your view, what are the problems or advantages with the current regulatory settings in respect to inhibitors?
Q3. How significant are these problems?
Q4. What evidence do we need to examine to inform further analysis of the problems? Is this evidence readily available?

Comment: Questions 1-4

7. The Association agrees that the range of inhibitor products currently available on the market are not covered directly by the Act.

8. The risks to New Zealand agriculture's international trade and reputation is too great to allow the development and application of new products for the primary sector without the appropriate oversight and controls under the Act and associated regulations.

9. The Association recognises that new product groups are being brought to the market with new use applications. Internationally, the laboratory test methods for detecting compounds is becoming more sophisticated. The risks of failing to meet international food safety limits and trade expectations could significantly and permanently undermine New Zealand's exports of primary produce with devastating economic consequences to New Zealand. And yet, the ready access and use of these new products groups must be managed and enabled so that industry can benefit from application of new and improved agricultural compounds.

10. The evidence for benefits of existing and new inhibitor products is clear through research provided on the potential reduction in nitrate leaching and atmospheric nitrous oxide emissions by a wide range of nitrification inhibitors. Similarly, urease inhibitors have been utilised for decades, to reduce volatilisation losses (and therefore leaching losses and greenhouse gas emissions). The decades of research into methane inhibitors to be fed to livestock to reduce enteric methane emissions provide a potentially ground-breaking opportunity for addressing agricultural greenhouse gas emissions. However, MPI have advised that products used for environmental mitigation are not covered by the Act.

11. The clear risk to international reputation was demonstrated when residues of the nitrification inhibitor product DCD were detected in milk, despite this compound having been used in agricultural settings for decades and with a known toxicological risk profile which was sufficiently low that there were no internationally defined (Codex) maximum residue limits. The consequence was that a default of zero applied and international backlash against agricultural produce with any residue was steadfast and firm.

12. To this end, adequate processes, resources and monitoring will be required by the industry and regulatory bodies alike to provide robust scientific systems and support for the use of these products to ensure they meet human, animal health and international trade requirements.

Summary Conclusion to Questions 1-4: Problem definition

13. The broad description of the problem describing the lack of adequate oversight and control of currently known and potentially new inhibitor products for use in agricultural production is supported.

14. New Zealand needs a robust regulatory system for products introduced for environmental mitigations to ensure that these products meet human, animal health and international trade requirements.

15. Inhibitor products are beneficial and effective tools in the challenge of reducing greenhouse gas emissions and nitrate leaching from agricultural systems. There is a genuine urgency to have robust systems in place to support and enable their safe use and application in New Zealand primary production.

Questions on definition of an inhibitor

Q5. Which of the definitions above do you prefer, and why?
Q6. 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?
Q7. Are you aware of any definition used internationally that could be relevant to New Zealand?
Q8. Should the definition for an inhibitor be outcomes based? Why or why not?
Q9. 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?
Q10. How would you define an inhibitor?
Q11. What else should be considered in relation to how an inhibitor should be defined?

Comment: Questions 5-11

16. The discussion paper introduces just two options for definitions for "inhibitors". These are based on a) outcomes provided, b) more prescriptive mode of action, as follows:

    a) *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.*

    And

    b) *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.*

17. In both cases the one term "inhibitor" is intended to cover a very wide range of product types, each with different product applications, different modes of actions and different outcomes.

18. For **option a**) the outcome-based definition, there remains a risk that any substance, mixture of substances, or biological compound intended to be used in the agricultural setting which mitigates any environmental or climate change impacts could be defined as an inhibitor.

19. If the intention is that an inhibitor impacts on biological processes/emissions to mitigate environmental or climate change impacts then it should be clear in the definition.

20. For **option b**), the prescriptive definition, is specific and prescriptive, meaning that it is not future proofed and could inadvertently mean that useful products and processes developed in the future might be excluded.

21. Neither of the proposed examples a) or b) for definition of inhibitor in the discussion document are supported with their current wording.

22. A hybrid approached whereby the Act provides for a broad, **outcome** based definition, and regulations provide for more prescriptive sub-classes of inhibitors based on their characteristics may be more satisfactory. An outcome based definition in the Act could be :

> *Inhibitor – Any substance, mixture of substances, or biological compound, used or intended for use on soils, plants or animals, or to be applied to the place where soils, plants or animals exist, or to the feed or water ~~on or in~~ which ~~there are~~ plants or animals consume, for the purposes of –*
> *influencing biological processes to mitigate environmental, sustainability, and/or climate change impacts*

23. We recommend that further differentiation is provided in the regulation based on mode of action and claims.

24. If the definition applies to all processes equally then the controls would necessarily apply equally and universally to all products regardless of whether it is applied to the soil where there is a urine patch, or to the coating of a fertiliser product or to the product fed to a ruminant animal.

25. In this regard, it is troubling that the discussion document outlines on page 2, that 'out of scope' for consideration in this consultation are:

    - *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;*

    - *management of residues if they are regulated as agricultural compounds such as under Maximum Residue Levels (MRLs), which are regulated under the Food Act 2014;*

26. The Association considers that: the nature of the inhibitor, its definition under the Act, how it would be categorised in regulation and how controls and any residues might be addressed, need to be considered in an integrated way.

27. We propose that the regulations categorise inhibitors into sub-groups. Sub-group characteristics could be based on mode of action or product claims.

28. International examples of prescriptive definitions are available for different types of inhibitors based on their mode of action and intended purpose.

29. The European regulation applies specifically to a 'Fertilising Product', recognising differences for various 'inhibitors'. (Ref: Page L170/53 of Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019.)

30. Methane inhibitors do not feature in this example from European Commission's fertiliser regulations. A definition for methane inhibitor should be specific to its purpose or claim and be provided for in a manner which is consistent with the application of definitions for other types of inhibitors.

31. The wording and text for definitions and sub-categories applied in a New Zealand context under the Act, and regulations, may need to be very different, but a clear definition based on mode of action and purpose for a range of product types is demonstrated by this European example.

32. More consultation on definitions in the regulations will be required.

Summary Conclusion to Questions 5-11: Definition of Inhibitor

33. Neither of the proposed definitions are supported as currently worded.

34. We propose a broad, outcomes-based definition in the Act, and developing subcategories for inhibitors in the subsequent regulations based on mode of action or claim.

35. We support a modified definition in the Act as follows:

> *Inhibitor – Any substance, mixture of substances, or biological compound, used or intended for use on soils, plants or animals, or to be applied to the place where soils, plants or animals exist, or to the feed or water which plants or animals consume, for the purposes of –*
> *influencing biological processes to mitigate environmental, sustainability, and/or climate change impacts*

36. Declaring certain considerations as 'out of scope' for this discussion paper has added to the difficulty in our response.

37. Our view is that consideration of: '*exactly how inhibitors would be managed if regulated under legislation and the management of residues if regulated as agricultural compounds,'* is core to consideration of how inhibitors are defined under the Act. The implications of the proposals cannot be assessed in the absence of this information.

38. Clearly these matters need to be considered in an integrated way when deciding on definitions and application of controls on inhibitors.

Transitional Period

OPTION 1: MAINTAIN THE STATUS QUO
Proposed transitional period
This option requires no transitional period.

OPTION 2: INDUSTRY INCREASES MANAGEMENT OF INHIBITORS
Proposed transitional period
This option would not require a transitional period as all products would still be allowed for sale under existing regulations. Individual companies, and possibly relevant industry groups with interests in inhibitors, would need to develop their own management and stewardship programmes for each product or product type.

OPTION 3: CHANGE THE REGULATION OF INHIBITORS
Proposed transitional period
If inhibitors are declared to be agricultural compounds, the default authorisation mechanism would require their registration unless they are exempted from registration via regulations under the ACVM Act.
If inhibitors require registration, a transitional period for inhibitor products already in the market would likely be required. A transitional period is the period of time that inhibitor products that are already in the market would be allowed to stay in the market without ACVM registration.
The transitional period allows time for companies to generate the data that would be required to meet registration requirements, for example data on residues, efficacy, or to support chemistry and manufacturing information requirements and prepare registration packages.
When the transitional period expires, no products making an inhibitor claim would be legally allowed to be in the market, unless registered. For the avoidance of doubt, no products would be 'grandfathered' into the new regime.
The transitional period would not apply to products that are not yet in the New Zealand market (as evidenced by the product being sold in New Zealand). Any new inhibitor products to the New Zealand market (imported, manufactured, sold, or used) would require registration from the date any change comes into force.

Questions on transitional period

Q12. Do you agree that a transitional period for products exempt from registration is unlikely to be required? Why or why not?
Q13. Are you supportive of a transitional period for products requiring registration? Why or why not?
Q14. 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?
Q15. 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?
Q16. 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.
Q17. 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?
Q18. 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.

Comment: Questions 12- 18.

39. 'Section 4: Options', recommends three options to consider: Status Quo; Industry Management of Inhibitors; Regulation of Inhibitors.

40. Only the 3rd option, 'Regulation under the Act requires a transition period for existing products currently on the market.

41. Application of a transition period for existing products, currently on the market, is crucial to ensure that farmers and growers maintain access to these mitigation products. However, the proposed transition time may be too short to allow additional New Zealand trials or labelling changes to be implemented by internationally suppliers.

42. There is a risk that advanced notice of a transition period may see a rush of new unproven products brought onto the market in advance of changes to the Act.

43. Introduction of regulation should ensure protection against 'gaming' to introduce new product in advance of the regulation. This could be achieved by defining clearly the date at which 'existing" products on the market is assessed, and this date could be retrospective, and supported by evidence of product availability.

44. Whether 2 years is appropriate depends on the level of detail and requirements needed to meet registration criteria, e.g. toxicology, efficacy, residue data etc. In the absence of clear direction of the regulatory approach that MPI will take it is impossible to estimate the requirements. Up to 5 years may be required to gather New Zealand specific data.

45. For existing products which have been in use over some time, it is expected that manufacturers and sellers will have accessed international and national data and science supporting use, and identified potential risks.

46. We suggest that MPI take an "actively managed transition" approach for existing products.

47. Suppliers of existing products should be required to provide evidence of current assessment of products to demonstrate that they have already considered key risk areas of animal health and food product residue, to support continued use.

48. Additional evidence will be required for registration. The period required for transition and registration of existing products will depend on both the process and the threshold of data required. The transition timeframe could be better addressed through the regulations, once there is a better understanding of the process required. It would therefore be better to specify a transition period if amending the scope of the Act – which could then be shortened through the regulatory process. We propose that five years is an appropriate default transition period.

49. An increase in registration of products is likely to add pressure to a regulatory system which already has a high burden of pressure to process new product registrations for agricultural chemicals. If this regulation pathway is taken, it must be supported by capability to process and manage applications in an efficient and timely manner.

50. In the absence of good controls on new 'inhibitor' products the risks to New Zealand trade in agricultural produce is very significant. The benefits of good controls could be great. Therefore, timely and efficient capability to process registration applications, warrants MPI investment in the necessary resources.

Summary Conclusion to Questions 12-18: Transitional Period

51. Transitional period for bona-fide product currently in the market is supported, however 2 years may be too short a time period. Up to 5 years may be required to gather New Zealand specific data.

52. Protection against a rush of new products being introduced prior to regulatory requirements will be required.

53. An "actively managed transition" for existing products should apply. (e.g. evidence of current assessment of products to demonstrate that they have already considered key risk areas of animal health and food product residue, to support continued use).

54. To prevent adverse outcomes of a flood of new products trying to enter in advance of registration requirements, suppliers of existing products should register evidence that products are currently on the market at a specified date.

55. Suppliers of existing product provide evidence of current assessment of those existing products to support that they have already considered key risk areas of animal health, food product residue and trade risks.

56. Staffing investment and capability of MPI for registration of products in an efficient and timely manner will be crucial to successful introduction of new inhibitor products

Questions on criteria
Q19. Do you agree with the proposed criteria? Why or why not?
Q20. Would you propose any other criteria not covered?

Comment: Questions 19 - 20.

57. Five criteria have been identified for assessing the proposed options. These are:

    1. *Manages risks to plant and animal health*
    2. *Manages risk to food safety*
    3. *Manages risk to trade*
    4. *Provides information and confidence to users and policy agencies*
    5. *Cost effectiveness*

58. The criteria listed are all supported as essential, and managing the risks presented by new products is the highest priority. Managing the risks from agricultural compounds and ensuring suitable consumer information is the purpose of the ACVM Act.

59. Consideration of not just the risks, but also the potential benefits provided by the proposed inhibitors could also be part of the assessment of the options. This could have an influence on cost effectiveness.

Summary Conclusion to Questions 19-20: Criteria for Assessing the Proposal

60. The chosen criteria for assessing options are supported. While managing the risks as described is a priority, recognising the potential benefits of inhibitors may influence assessment of cost effectiveness of options.

Questions on the proposed options

Q21. 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.
Q22. 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.
Q23. 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.
Q24. 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?
Q25. 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?
Q26. Do you currently import, manufacture, or sell inhibitors? What would the impact of implementing **option 3** and requiring registration of inhibitors have on your business? How much product would be affected? What do you estimate would be the cost?

Comment: Questions 21- 26.

61. Of the proposed options a clear preference rests with Option 3.

62. Inhibitors should be defined as agricultural compounds and regulated under the ACVM Act to ensure that risks to food safety, plant and animal health, and trade are sufficiently managed. Legal obligations would apply.

63. New Zealand is unique amongst OECD countries in that agricultural product and trade in primary products is central to New Zealand's export revenue. New Zealand has a reputation for producing safe, high-quality food products. If this reputation is lost through transgression of food standards or environmental responsibilities, it will be very difficult to recover this market advantage. As such, the economic consequence to New Zealand of failing to manage agricultural compounds diligently would be very significant.

64. Robust controls which apply right across the primary sector, are not just warranted, but essential. The status quo is recognised as unacceptable and it is wholly inadequate to rely on just those parties with a good stewardship programme in place to protect all of New Zealand agricultural production and trade.

65. The discussion document provides an assessment of the options which concludes that only Option 3 protects against market failure.

66. The risks to New Zealand's export base are far too high to rely on good will and stewardship alone. While the costs of regulation (either with registration or conditions for exemption from registration) might be high, these costs are justified relative to the cost of failure in international market acceptance and loss of reputation for providing safe, good quality food products.

67. While a number of companies may well provide adequate assurance under a well-managed stewardship programme, there are also a very large number of smaller importers and supplies of agricultural compounds, which could include any number of inhibitor products. Controls and systems are required which adequately manage the identified risks in a manner that is consistent with the purpose of the ACVM Act. It is identified in the discussion document that Options 1 and 2 cannot reliably meet this need. We support that assessment.

68. The Association considers that prompt action is required to address the immediate demand and need for inhibitors in the market to address environmental as well as production demands.

69. To that end, rather than the protracted process of amending the ACVM Act to enable inhibitors to be included as agricultural compounds, a more rapid process of 'Declaration by Order in Council' is supported.

70. Within Option 3 – regulation under ACVM, there remains a further option as presented in question 21 – exemption from registration.

71. Once declared an agricultural compound under the ACVM Act, the option remains to list the inhibitors as exempt from registration, as occurs with fertiliser products subject to conditions listed in Schedule 2 of the associated regulations.

72. To ensure satisfactory control of inhibitors and meet the Purpose of the Act, the Association supports regulation of inhibitors. We note that some inhibitors, e.g. urease inhibitors, have been successfully in use for quite some time, with no known issues arising. It is critical that the level of regulatory control and registration requirements reflect the potential risk of a product.

73. Over one third of all urea sold in New Zealand is coated in a urease inhibitor (approximately 250,000 tonnes of product), and this proportion has been steadily increasing. At current prices this amounts to a retail value of over $155,000,000

74. Urease inhibitors are currently the only greenhouse mitigation option for nitrogen fertilisers which is recognised in the National Inventory for Greenhouse Gas Emissions. This availability of urease is critical to support farmers and growers attempts to reduce emissions.

75. The greater efficiency of coated urea allows farmers to use less nitrogen, so again contributes significantly to achievement of government goals on freshwater.

76. We strongly support option 3 as we consider that a clear pathway for regulation of inhibitors is critical to enable both continued use of existing commercially available inhibitors with confidence, and also to create a clear innovation pathway for new

inhibitors. It is critical that that our international trading partners have confidence in the robustness of New Zealand's regulatory approach.

Summary Conclusion to Questions 21-26: The Proposed Options

77. Option 3 – regulation of inhibitors under ACVM Act, by declaring Inhibitors as agricultural compounds is preferred.

78. The economic consequence to New Zealand of failing to diligently manage inhibitors (as agricultural compounds) could be very significant. Noncompliance with international trade requirements such as food standards would be unacceptably damaging to New Zealand's reputation and export opportunities.

79. Due to the importance of prompt access to inhibitors for the environmental as well as production benefits they offer, an expedient process, such as declaration by Order in Council, is supported.

80. Once declared a "agricultural compound", the further option to provide exemption of inhibitors from registration as a whole, is generally opposed.

81. A clear definition of inhibitors, providing for different types of inhibitor is required and the level of regulatory control and registration requirements should reflect the potential risk of a product.

Questions on efficacy

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

Q27. A minimum level of efficacy should be required for all inhibitor products, and if so, what this should be;
Q28. No minimum level of efficacy should be required, but the specific effect being claimed must have sufficient scientific evidence to support it;
Q29. Only specific claims should be approved (as determined by trial data, e.g. 'reduces methane by X% on average [in XYZ conditions]);
Q30. Only general claims should be approved (e.g. 'reduces methane', rather than a specific quantitative claim);
Q31. Only graduated levels of general efficacy claim should be allowed on the label (e.g. reduces X by an average of 0-10%; reduces X by an average of 10-20%. Which 'level' a product could claim would be determined by the trial data);
Q32. There are alternative options that should be considered for efficacy requirements, or other matters that should be taken into consideration? If so, please provide a description of that option, reasons for supporting that option and its advantages and disadvantages.

Comment: Questions 27- 32.

82. The discussion document states that demonstration of efficacy along with product safety is required under the registration of an agricultural compound. However, the proposed options bundle a range of different types of inhibitors under one definition.

This approach is likely to make it very difficult to adequately describe efficacy standards for the purpose of regulation under ACVM Act.

83. Instead we propose that efficacy is assessed against claims, and there should be no minimum level of efficacy. If there is a claim for a product that it reduces emissions by a certain percentage, data and field trials should support this argument. It is important that such claims consider the system context so the real benefit to NZ agriculture is clear.

84. For example, in terms of climate change benefits, it is recognized that even a small reduction (5% or less) of methane or nitrous oxide emissions can be valuable at national scale, if there is widespread use. Hence, to facilitate adoption of inhibitor products, it may be beneficial if ACVM is not tied to a minimum performance level, but requires robust evidence of claims. Claims must be based on labelled use and the specific registration conditions under which the product is used.

85. Efficacy data should be provided by robust scientific assessments, as is standard for of agricultural compounds.

86. The declarations and standards for each type of product may be very different, (e.g. a methane inhibitor should not be defined by the efficacy standards which are appropriate for a nitrification inhibitor).

87. Guidance will need to be provided on the nature of evidence required, and whether robust and reputable international data can be utilised for registration of products to be used in New Zealand.

88. As discussed above, the weight of evidence required may be different for inhibitor products which have been successfully used for some time in New Zealand without issues. (e.g. urease inhibitors as an additive/coating to fertiliser products).

89. Efficacy requirements may need to be addressed subsequent to decisions on how inhibitors are to be defined and intended to be controlled, if Option 3, 'Regulation' is accepted.

90. However, it is noted that efficacy and appropriate claims are also regulated under Commerce Act, providing further controls and safeguards.

91. There needs to be coordination in process and regulations affecting climate change emissions. We note that the approval process under the Act should also be considered in terms of verified emissions reduction effectiveness under the Climate Change (Agriculture Sector) Regulations. For example, where efficacy assessment are carried out under the National Inventory processes and also accepted under the ETS regulations. Otherwise there is a risk of duplication of process between the Act, MPIs greenhouse gas inventory process and the development of emissions factors under the ETS.

Summary Conclusion to Questions 27 – 32: Efficacy

92. We propose that efficacy is assessed against claims, and there should be no minimum level of efficacy.

93. Guidance is needed on the level of evidence required, and whether robust and reputable international data can be utilised.

94. There needs to be coordination in process and regulations affecting climate change emissions with links to other MPI processes to reduce the risk of duplication. For example, where efficacy assessment are carried out under the National Inventory processes and also accepted under the ETS regulations.

MPI's preliminary position

	Manages health risks	**Manages food safety risks**	**Manages trade risks**	**Informs users**	**Cost effectiveness**
Option 1: Status Quo	No	No	No	No	Not at a national level
Option 2: Increasing industry management of inhibitors	To some extent	To some extent	To some extent	To some extent	To some extent
Option 3: Change regulation of inhibitors to include them under ACVM Act	Yes	Yes	Yes	Yes	Yes, at a national level

MPI's preliminary position is that inhibitors should be brought within the scope of the ACVM Act so their risks in relation to the risk areas of section 4 of ACVM Act can be managed effectively.

This option also minimises economic and reputational risks, and the assurance increased regulation offers to product-users is likely to be commercially advantageous compared to the status quo.

Changing regulation is preferred over the status quo and increasing industry management of inhibitors options, as:

- there would be a more consistent approach to the management of inhibitors;
- reputational and direct commercial risks would be comparatively better managed;
- there would be clearer regulatory rules for importers, manufactures, distributors and end users of inhibitors to ensure they are fit for purpose;
- the New Zealand Maximum Residue Level Notice set under the Food Act 2014 will apply to residues of inhibitors in food commodities;

- there would be robust legal mechanisms to prevent entry of ineffective or otherwise unsuitable inhibitors into the market, and/or to manage compliance incidents (e.g. residue violations);
- regulators would have more information about inhibitors, for example should there be future trade or residue issues;
- better management of the identified risk areas would be economic from a national perspective (e.g. through helping to avoid negative impacts on trade);
- there would be more consistent provision of sufficient consumer information about inhibitors; and
- companies would have legal obligations under the ACVM Act.

Registration of inhibitors would be our preferred risk management option under the ACVM Act, as opposed to them being exempt from registration, as this would better facilitate environmental outcomes and be beneficial from a consumer information perspective.

Q33. Do you agree with the evaluation of options against criteria as presented in Table 1? If not, why not? Please provide detail to support your answer.

Comment: Question 33: MPI's Preliminary Position

95. The general assessment provided by MPI's preliminary preference for regulation under the ACVM Act and for inhibitors not being exempt from registration is, in general, consistent with our position, except that;

A) The definitions for the range of different types of inhibitors taking into account their purpose and mode of action requires more detailed consideration.

Both definitions proposed in the discussion document may create problems with practical application of regulation to a wide range of inhibitors with very different modes of action and uses. This may be addressed by having a broad outcomes based definition in the Act and developing subcategories for inhibitors in the subsequent regulations based on mode of action or claim.

B) Consideration of matters deemed "out of scope" have a considerable bearing on matters to be addressed, such as how inhibitors would be categorised, the data and information needed to register products under the ACVM Act, which food residues might need to be addressed and how, and whether these categories present greater levels of risk for some inhibitor products than others. These considerations impact on the issues such as the transition period, currently proposed for 2 years.

At the same time, any transitional period must avoid a surge of new product being introduced in advance of regulation taking effect.

Adequate resourcing by MPI to support registration of new products efficiently and in a timely manner is essential if regulation is to be accepted as the best pathway forward.

Concluding Comments

96. Thank you for the opportunity to provide feedback on the current considerations and proposals for regulation and control of the use of inhibitors in New Zealand primary production.

97. The Association and our member companies welcome the opportunity for further detailed discussion on the use of inhibitors in agriculture and how best to address the issues and concerns raised in this feedback.

Greg Sneath

Executive Manager

Fertiliser Association of New Zealand Date: 3 April 2020