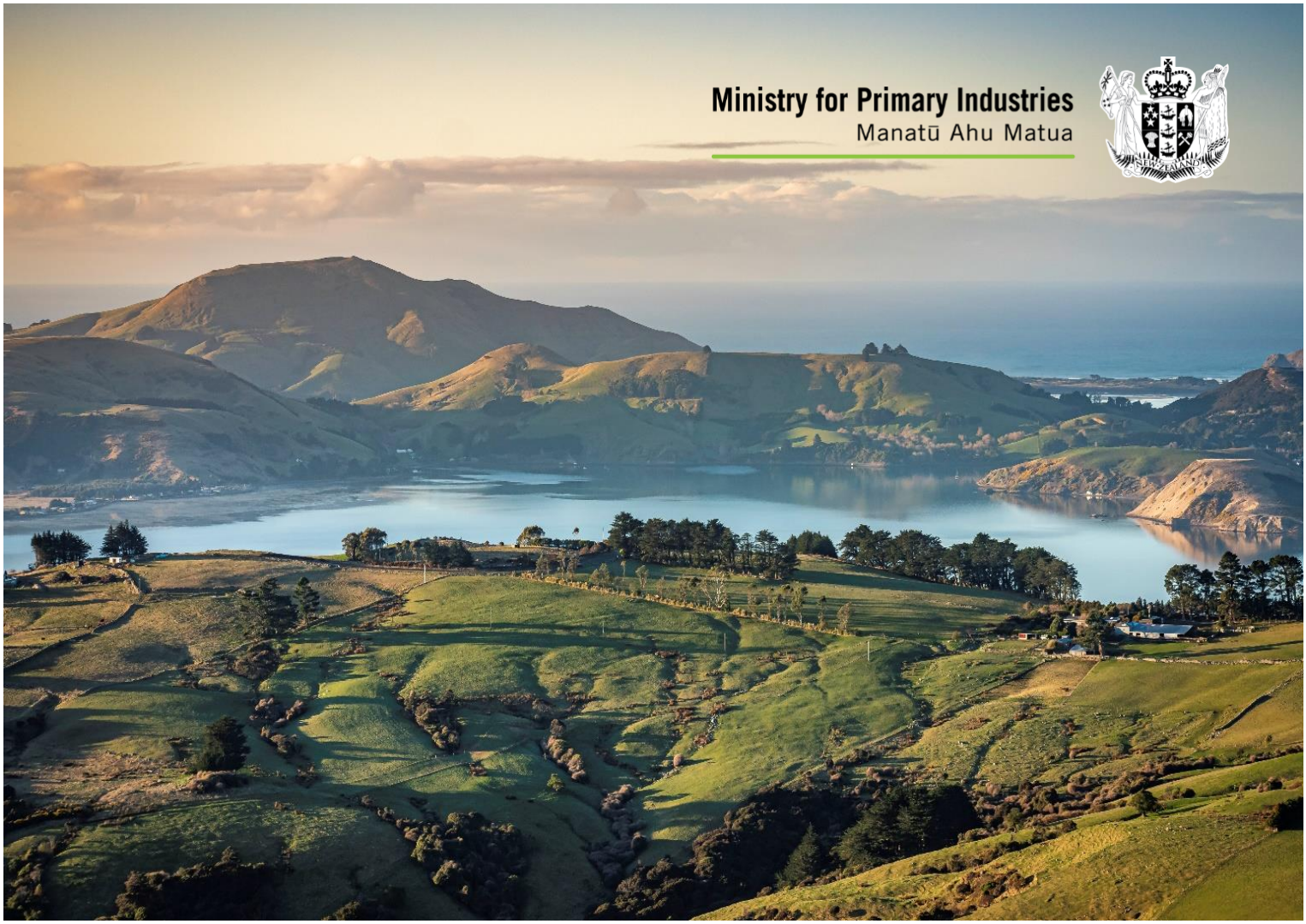

The regulation of inhibitors used in agriculture

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This publication is also available on the Ministry for Primary Industries website at http://www.mpi.govt.nz/news-and-resources/publications/

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Making submissions

The Ministry for Primary Industries (MPI) is seeking feedback on the proposed options for regulating inhibitors used in agriculture.

Have your say

You can send your submission to us in any of the following ways:

Email Please email your feedback to: Food.Policy@mpi.govt.nz

Letters While we prefer email or online submissions, you can send your response by post to:

Consultation: Inhibitor regulation
Ministry for Primary Industries
PO Box 2526
Wellington 6014

Submissions must be received by MPI no later than 5:00pm on 27 March 2020.

Please include the following information:

- your name and title
- your contact details (your phone number, address, and email)
- your organisation's name (if you are submitting on behalf of an organisation)

Your feedback is public information

Any submission you make becomes public information. Anyone can ask for copies of all submissions under the Official Information Act 1982. The Official Information Act says we must make the information available unless there is a good reason for withholding it. You can find those grounds in sections 6 and 9 of the Official Information Act.

Tell us if you think there are grounds to withhold specific information in your submission. Reasons might include that it is commercially sensitive or personal information. Any decision MPI makes to withhold information can, however, be reviewed by the Ombudsman, who may require the information be released.

1 Executive summary

Use of inhibitors in agriculture

Many New Zealand farmers are looking for ways to reduce their nutrient losses and greenhouse gas emissions. In particular, the Climate Change Response (Zero Carbon) Amendment Bill and the Essential Freshwater proposals have increased interest in the potential for inhibitors to help achieve these goals. However, use of inhibitors can pose risks to trade, food safety and animal and plant health. Currently New Zealand does not regulate inhibitors in a way that manages all of these risks. Farmers and wider industry want to make sure there are no negative impacts from 'trying to do the right thing' in response to regulatory signals, and would also like assurance that products on the market that claim to be inhibitors are effective.

Why we are reviewing the regulation of inhibitors

This discussion document identifies options to alter the regulatory oversight of inhibitors so that the primary sector is better able to safely and effectively use inhibitors to mitigate environmental, sustainability and climate change issues. It also discusses some key details that must be determined should the level of regulatory oversight of inhibitors increase.

Options for altering the regulation of inhibitors used in agriculture

MPI has identified, and is seeking feedback on, two options for altering the management of inhibitors used in agriculture, in addition to the status quo:

> **Option 1** – **the status quo** does not alter how inhibitors are regulated in any way. It involves the least compliance cost to industry and maintains current access to inhibitors.
>
> **Option 2** – **increased industry stewardship of inhibitors** is a non-regulatory option. It would require those involved in selling inhibitors working with users to ensure there is sufficient information provided to manage risk to animal and plant health, food safety, and trade.
>
> **Option 3** – **changing the regulation of inhibitors**. Inhibitors could be identified as agricultural compounds and the risks managed by assessments under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM).

Your feedback

Submissions are being sought on:

- whether regulatory oversight of inhibitors should be increased (or whether, in your view, better alternatives exist) or not;
- whether the most appropriate options to increase management or regulatory oversight of inhibits have been identified;
- key regulatory settings should oversight increase;
- the impacts of any the identified options; and
- any potential unintended consequences of any of the proposed options.

What is in scope for this review?

This consultation looks at proposed changes to New Zealand's current approach to regulating inhibitors used in primary production.

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;
- 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;

- proposals to amend Codex Alimentarius[1], as this review is focused on the regulation of inhibitors in New Zealand;
- proposals to amend the Hazardous Substance and New Organisms Act 1996 (HSNO Act), as this would require fundamental changes to that Act;
- proposals to amend the New Zealand Agricultural Greenhouse Gas Inventory methodology, as this methodology is independent of substance and biological compound regulatory regimes in New Zealand; and
- how inhibitors should be incorporated in Overseer (determined by Overseer Ltd) or any other models.

Your feedback

We are seeking your feedback on whether to alter the regulation of inhibitors used in agriculture in order to reduce the risk to food safety, animal and plant health and trade, when these products are used. Your submissions will be used as one of the inputs to further inform our policy work.

[1] The Codex Alimentarius is the collection of food standards and related texts adopted by the Codex Alimentarius Commission, which are established to protect the health of the consumers and to ensure fair practices in the food trade.

2 Introduction

This discussion document looks at whether New Zealand would benefit from a different approach to regulating inhibitors used in agriculture. It seeks your feedback on the options proposed to improve the regulation of inhibitors, how inhibitors should be defined, and issues related to implementation should regulatory oversight increase.

2.1 CURRENT REGULATORY REGIME

There are already inhibitor products that reduce greenhouse gas emissions or nutrient losses to water in the New Zealand agricultural market. Most of these are regulated under the Hazardous Substances and New Organisms (HSNO) Act 1996, the purpose of which is to protect the environment and the health and safety of people and communities by preventing or managing the adverse effects of hazardous substances and new organisms. However, HSNO does not manage risk to trade from residues (as occurred with dicyandiamide (DCD)[2]), animal or plant safety, human dietary exposure (food safety) or efficacy, which are covered by the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and the Animal Products Act 1999[3].

The environmental purpose of inhibitors is outside the definition of an '*agricultural compound'* in the ACVM Act (which covers among other things pesticides, veterinary medicines, vertebrate toxic agents, fertilisers, and pet and animal feeds). Inhibitors are, therefore, not regulated under the ACVM Act, leaving a regulatory gap in relation to management of the risks identified above.

2.2 HAZARDOUS SUBSTANCES AND NEW ORGANISMS ACT 1996

The HSNO Act, which is administered by the Environmental Protection Authority (EPA), aims to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.

2.2.1 What is a hazardous substance?

Hazardous substances are defined in the HSNO Act as:

> "Hazardous substance means, unless expressly provided otherwise by regulations or an EPA notice, any substance:
>
> (a) with 1 or more of the following intrinsic properties:
>
> (i) explosiveness:
>
> (ii) flammability:
>
> (iii) a capacity to oxidise:
>
> (iv) corrosiveness:
>
> (v) toxicity (including chronic toxicity):
>
> (vi) ecotoxicity, with or without bioaccumulation; or
>
> (b) which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any 1 or more of the properties specified in paragraph (a)."

Hazardous substances include agrichemicals, cosmetics, industrial chemicals, household cleaning products, petrol, explosives, and fireworks. They also include inhibitor products if they meet the hazardous substance criteria. Hazardous substances must be approved by the EPA before they can be used in New Zealand. When a hazardous substance is approved, the EPA puts in place controls on

[2] In late 2012, very low levels of the nitrification inhibitor dicyandiamide (DCD) were detected in milk. Although DCD was not considered to pose a food safety risk, this resulted in consumer concerns and reactions from some importing countries that impacted trade. In response, the fertiliser industry agreed to voluntarily suspend commercial sales of DCD because of the trade risk.

[3] The Animal Products Act 1999 regulates the export of animal commodities; residues of inhibitors in animal commodities are managed to ensure compliance with importing country requirements. However, providing for export requirements is not linked to how a chemical is regulated domestically.

the labelling, packaging, storage, distribution, use and disposal of the substance to manage risks associated with its use. Some hazardous substances also require authorisation under the ACVM Act.

2.3 AGRICULTURAL COMPOUNDS AND VETERINARY MEDICINES ACT 1997

The ACVM Act aims to prevent or manage risks associated with agricultural compounds, including risks to trade in primary produce, risks to public health, risks to animal welfare and risks to agricultural security. A further purpose of the ACVM Act is to ensure that the use of agricultural compounds does not result in breaches of domestic food residue standards, and that sufficient consumer information about agricultural compounds is available.

Registration of agricultural compounds requires a risk assessment involving the evaluation of data specifically related to the use of the substance, that is of sufficient quality to provide confidence in the assessment. This assessment of a specific product (which can include multiple substances) under the ACVM Act differs from the assessments of chemicals conducted under HSNO (as the risk areas considered are different).

The ACVM Act has a relationship with other Acts. Generally, the outcomes for which ACVM regulates are those set under other related Acts. For example, maximum residue levels for food products are set under the Food Act 2014, but the ACVM Act sets the controls on agricultural compounds to ensure the Food Act residue level is not breached.

2.3.1 What is an agricultural compound?

The ACVM Act defines an *agricultural compound* as:

"(a) any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which the plants and animals are managed, for the purposes of:

(i) managing or eradicating pests, including vertebrate pests; or
(ii) maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or
(iii) fulfilling nutritional requirements; or
(iv) the manipulation, capture, or immobilisation of animals; or
(v) diagnosing the condition of animals; or
(vi) preventing or treating conditions of animals; or
(vii) enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or
(viii) marking animals; and

(b) includes:

(i) any veterinary medicine, substance, mixture of substances, or biological compound used for post harvest treatment of raw primary produce; and
(ii) anything used or intended to be used as feed for animals; and
(iii) any substance, mixture of substances, or biological compound declared to be an agricultural compound for the purposes of this Act by Order in Council made under subsection (2)"

Whether a product meets the definition of an agricultural compound depends mainly on its use. If the product is not intended to be used to manage plants or animals for a specified purpose, it is not considered an agricultural compound. For example, a compound used to control an animal disease would be considered an agricultural compound, but a compound used to control a human disease would not.

Some substances that are inhibitors could also be used as agricultural compounds. However, these substances are not considered agricultural compounds if their stated purpose (i.e. their label claim) does not meet the definition of agricultural compound under the ACVM Act. Furthermore, a substance used as an agricultural compound, such as a fertiliser, that is also used as an inhibitor means that its use as a fertiliser is regulated under the ACVM Act, but its use as an inhibitor is not.

To import, manufacture, sell, or use an agricultural compound in New Zealand, it must be authorised. If an agricultural compound is a hazardous substance or new organism, it also requires approval

under the HSNO Act. Where the agricultural compound is also a prescription human medicine, it requires the approval by the Director-General of the Ministry of Health.

2.4 THE PROBLEM

There is no definition of what an inhibitor is, and there is no barrier to entry for inhibitor products to the New Zealand market, provided they have the appropriate HSNO approval. This lack of specific regulatory oversight of inhibitors means that:

- there are no clear regulatory rules for importers, manufactures, distributors and end users of inhibitors to ensure they are fit for purpose (e.g. efficacy, residues, safety to plants and animals, and food safety);
- the New Zealand Maximum Residue Level Notice set under the Food Act 2014 does not apply to residues of inhibitors in food commodities (as they are not regulated as agricultural compounds);
- there are no 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);
- the activities of one company (e.g. that may result in residue violations) can present significant risks to New Zealand's trade, other businesses, and the wider economy;
- there is a risk of an over reliance on manufacturers to manage product stewardship in MPI risk areas such as trade and residues;
- production sectors may consider that they are exposed to trade and residue risks, as occurred with DCD;
- New Zealand could potentially be left behind if overseas regulatory bodies commence a higher level of regulatory oversight of inhibitors;
- regulators have little information about inhibitors should there be future trade or residue issues, making a response difficult to manage; and
- there is a risk that robust data on the use of inhibitors will not be gathered or verified, making it difficult to verify their effectiveness and effects.

What do you think?
Questions on problem definition 1. Do you agree with this characterisation of the problem? If not, why not? 2. In your view, what are the problems or advantages with the current regulatory settings in respect to inhibitors? 3. How significant are these problems? 4. What evidence do we need to examine to inform further analysis of the problems? Is this evidence readily available?

2.5 THE OBJECTIVE OF THE REVIEW

The objective of this review is to consider the regulation of inhibitors, to ensure risks to plant and animal health, food safety and trade are being managed appropriately, and to ensure that users have access to the information they need to use inhibitors effectively, with confidence, and to minimise impacts on industry.

Inhibitors have high potential as a mitigation option to reduce agricultural greenhouse emissions and nutrient leaching. This review is important to help to avoid unintended negative impacts that can range in scale from affecting individual companies and users right through to New Zealand's economy and international reputation.

3 Definition of an inhibitor

Before considering options that may change how inhibitors are regulated, it is important to consider how 'inhibitor' should be defined.

Inhibitors vary widely in how and what they inhibit. Inhibitors are commonly considered to be compounds that restrict the processes of nitrification, denitrification, ammonia volatilisation, urease production, or methanogenesis (the formation of methane) in some way. For example, some types of inhibitors may be applied to pasture to reduce nitrate leaching, whereas other types of inhibitors may be added to feed to reduce methane emissions. There is no legislated definition for an inhibitor in New Zealand. In addition, there is no administrative definition associated with the ACVM Act, as inhibitors are not currently within the scope of the ACVM Act's '*agricultural compound'* definition.

We seek your views on how 'inhibitor' should be defined, or if inhibitor is the best term to use. The scope is broad both in the types of inhibitors (e.g. urease, methane) and biological/synthetic composition (e.g. vaccines, chemicals). They can be applied indirectly or directly to animals (e.g. via animal feed, water, vaccines) or to plants, or to land or waterways. It is very important that we get the right definition of inhibitor, otherwise it could include products that are not of regulatory interest, or exclude products that are of regulatory interest.

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.

What do you think?
Questions on definition of an inhibitor 5. Which of the definitions above do you prefer, and why? 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? 7. Are you aware of any definition used internationally that could be relevant to New Zealand? 8. Should the definition for an inhibitor be outcomes based? Why or why not? 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? 10. How would you define an inhibitor? 11. What else should be considered in relation to how an inhibitor should be defined?

4 Overview of proposed options for management of inhibitors

Note: for all options presented below, requirements from other legislation may still apply. For example, the product may still require approval under the Hazardous Substances and New Organisms Act 1996 (which includes an assessment of risks to human health and the environment). And if the inhibitor is being imported and contains ingredients of biological origin, it may also require a biosecurity assessment under the Biosecurity Act 1993. None of the options presented below impacts on other existing legislative requirements.

OPTION 1: MAINTAIN THE STATUS QUO

What this option covers

The 'status quo' maintains the current situation and does not change any aspect of how inhibitors are regulated.

How it would work

Inhibitors would still be regulated as hazardous substances under the HSNO Act (if they meet the criteria of a hazardous substance). These products would only be assessed under the ACVM Act in instances where their proposed use was not as an 'inhibitor' only, but also had a use that meets existing definitions under the ACVM Act (note that the product would only be assessed for the purpose that meets the existing definitions, and not for its use as an inhibitor).

Proposed transitional period

This option requires no transitional period.

OPTION 2: INDUSTRY INCREASES MANAGEMENT OF INHIBITORS

What this option covers

This option would involve those involved in selling inhibitors working with the users to ensure there is sufficient information provided to manage risk to animal and plant health, food safety, and trade.

How it would work

Companies would take a greater role in managing the risks posed by inhibitors, with the industry that imports and/or manufactures inhibitors taking more responsibility for stewardship of these products to manage the risks, e.g. via supplier agreements.

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

What this option covers

The regulation of inhibitors could be changed. Inhibitors could 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.

How it would work

The goal of risk management under the ACVM Act is to manage the risks posed by the use of agricultural compounds to an acceptable level, which will support the overall government goal of growing and protecting New Zealand. If risks cannot be managed to an acceptable level then the product does not get registered. Finding that acceptable level and managing risk to that level is the purpose of regulatory control of agricultural compounds. This is done through authorising and monitoring the sale, distribution and use of products. 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 come within the scope of the ACVM Act, no inhibitor may be used (including imported, manufactured or sold) in New Zealand unless it is authorised under the Act. There are two options available to bring inhibitors within the scope of the ACVM Act:

- Amend the definition of 'agricultural compound' in the ACVM legislation; or
- Declare inhibitors to be agricultural compounds via an Order In Council (as done for animal feed[4] in 2006)

Information note: Registration or exemption from registration

If inhibitors are brought within the scope of the ACVM Act, it needs to be determined which, if any, of the different types of inhibitors require registration.

A decision on whether some or all inhibitors could be exempt from registration would be subject to separate consultation after inhibitors are brought within the scope of the ACVM Act.

Inhibitors could be exempt from registration by adding them into schedule 2 of the Agricultural Compounds and Veterinary Medicines (exemptions and Prohibited Substances) Regulations 2011. The ACVM Act requires that the Minister should recommend an exemption if the likely cost of assessing and registering an agricultural compound is greater than the likely risks from the use of that agricultural compound[5] without registration, or if the risks are already adequately managed under other legislation.

If an agricultural compound is exempt from registration, certain obligations still apply to the import, manufacture, sale, or use of the product in New Zealand. These obligations are to ensure that the product is fit for its intended purpose, conforms to its specifications, and is represented truthfully and accurately.

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.

What do you think?

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.

[4] Animal Feed was defined in the Order In Council as:

> animal feed means any substance or preparation manufactured or prepared in whole or in part from 1 or more than 1 kind of grain, seed, plant, oil, juice, meat, fish, or other source of nutrient of any kind and used, or intended to be used, as food for stock, pets, or other animals; and includes any animal feed additive.

[5] i.e. to public health; trade in primary produce; to animal welfare; and risks to agricultural security.

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

4.1 OTHER OPTIONS CONSIDERED

Two other options were considered but rejected for the following reasons:

- *Altering the HSNO Act.* This option is not considered justifiable as it would require making fundamental changes to the purposes of the Act. This would potentially duplicate the ACVM Act, and would take a considerable period of time.
- *Establishing a new Act to regulate inhibitors*. This would require establishing an Act to regulate inhibitors. The establishment of a new Act would take considerable time and effort. It would also duplicate requirements set out in the ACVM Act.

5 Criteria for assessing the proposed amendments

The criteria that have been identified for assessing the proposed options are:

1. **Manages risks to plant and animal health**
    - will the intervention better manage potential risks posed to plants and animals through the use of these products?

2. **Manages risk to food safety**
    - will the intervention better manage potential risks to food safety when these products are applied to (or to the place where there are) food producing animals and plants?

3. **Manages risk to trade**
    - will the intervention better manage the potential risks to trade from the use of these products in agriculture?

4. **Provides information and confidence to users and policy agencies**
    - will the intervention provide the information users of inhibitors in agriculture need to use them safely?
    - will the intervention provide the information users of inhibitors in agriculture need to use with confidence that they will work as intended?
    - will the intervention assess the effectiveness of the proposed use of the products?

5. **Cost effectiveness**
    - will the intervention achieve the objective with minimal costs to government and the affected industry?
    - will the intervention provide a positive cost/benefit outcome?

What do you think?
Questions on criteria 19. Do you agree with the proposed criteria? Why or why not? 20. Would you propose any other criteria not covered?

6 Assessment of options against criteria

6.1 CRITERION 1: MANAGES RISKS TO PLANT AND ANIMAL HEALTH

Option 1 (Status quo): This option would not sufficiently manage possible risks to plant or animal health from direct application of inhibitors to livestock or plants, and/or inhibitors consumed by animals or humans. There would be no regulatory assessment to determine crop or animal safety. Importers, manufacturers, sellers, and users would not have to comply with any provisions in the ACVM Act that are designed to manage these risk areas.

Should there be market failure of an inhibitor, Government has limited mechanisms to intervene to rectify the failure and this would solely fall on market forces to manage this.

Option 2 (Industry increasing management of inhibitors): The risk posed by products used on plants and animals are most often managed by governments, unless the risks are very small (as for exempt ACVM products). Increased stewardship of products by importers, manufactures, distributors, and/or sellers of the product would increase the degree to which risks to plant and animal health are managed, however, there may be inconsistency in approach between companies. Furthermore, there is no mechanism to enforce this, particularly in situations where product stewardship is considered inadequate. There would be no regulatory assessment to determine crop or animal safety. Importers, manufacturers, sellers, and users would not have to comply with any provisions in the ACVM Act that are designed to manage these risk areas.

Should there be market failure of an inhibitor, Government has limited mechanisms to intervene to rectify the failure and this would solely fall on market forces to manage this.

Option 3 (Changing the regulation of inhibitors): This option would sufficiently manage risks to plant and/or animal health, as these risks areas are specifically assessed and managed for under the ACVM Act.

Should there be market failure of an inhibitor, then Government has mechanisms to intervene to rectify the failure.

6.2 CRITERION 2: MANAGES RISK TO FOOD SAFETY

Option 1 (Status quo): This option does not sufficiently manage the food safety risks that may be present when using inhibitors in agriculture. Generally, it is the responsibility of Government to manage the dietary exposure of products used in food production. The mechanism normally used for this purpose is the establishment of Maximum Residue Levels (MRLs). However, this only applies to agricultural compounds, and therefore does not currently apply to inhibitors.

Should there be market failure of an inhibitor, Government has limited mechanisms to intervene to rectify the failure and this would solely fall on market forces to manage this.

Option 2 (Industry increasing management of inhibitors): This option does not sufficiently manage the food safety risks that may be present when using inhibitors in agriculture. Generally, it is the responsibility of Government to manage the dietary exposure of products used in food production. The mechanism normally used for this propose is the establishment of MRLs. However, this only applies to agricultural compounds, and therefore does not currently apply to inhibitors. Increased industry stewardship would therefore not sufficiently mitigate this risk.

Should there be market failure of an inhibitor, Government has limited mechanisms to intervene to rectify the failure and this would solely fall on market forces to manage this.

Option 3 (Changing the regulation of inhibitors): This option would sufficiently manage risks to food safety as an assessment under the ACVM Act includes a risk assessment for food safety. MRLs would then be determined to support good agricultural practice while ensuring food safety.

Should there be market failure of an inhibitor, Government has mechanisms to intervene to rectify the failure.

6.3 CRITERION 3: MANAGES RISKS TO TRADE

Option 1 (Status quo): The risk to trade from potential residues would continue, which poses a significant risk to New Zealand's overall reputation and trade status. Should there be an issue, it is likely that the negative impacts from one inhibitor product would have negative impacts on more than just the importer, manufacturer, seller, or user of that product. In most countries, the management of food commodities in trade, both for food safety and biosecurity purposes, is by Government – particularly where there are government-to-government obligations or agreements.

It is likely there will be increasing international expectations that Governments will intervene in this space, which means that there is a further reputational risk as well as direct commercial risk should residues be detected that remains unmanaged by this option.

Option 2 (Industry increasing management of inhibitors): Companies may have information available to help users manage some trade risks, but this may not be true for all manufacturers and importers of inhibitors. It is unlikely the risk would be consistently well managed. Should there be an issue, it is likely that the negative impacts from one inhibitor product would have negative impacts on more than just the importer, manufacturer, seller, or user of that product.

In most countries, the management of food commodities in trade, both for food safety and biosecurity purposes, is by Government, particularly where there are government-to-government obligations or agreements.

It is likely there will be increasing international expectations that Governments will intervene in this space, which means that there is a further reputational risk as well as direct commercial risk should residues be detected that remains unmanaged by this option.

Option 3 (Changing the regulation of inhibitors): Regulating products under the ACVM would assist in managing trade risk as standardised use patterns could be set, and MRLs would be legally required and determined to help mitigate any trade risk. The approach would be consistent across manufacturers, importers, and sellers. This would also assist New Zealand potentially negotiating the acceptability of uses and any potential resulting residues with other countries and the setting of international standards to help further mitigate trade risks, e.g. *Codex Alimentarius* on management of residues in food commodities.

6.4 CRITERION 4: PROVIDES INFORMATION AND CONFIDENCE TO USERS AND POLICY AGENCIES

Option 1 (Status quo): Only the information currently being provided by industry about their products would be available to users and other regulators. This information may not be sufficient to guide users in the use of these products as inhibitors, or to verify inhibitors' effectiveness and effect on the environment.

This approach does not support the users of inhibitors as they seek assurances that the products work, are safe to use, and will be acceptable for management programmes.

Option 2 (Industry increasing management of inhibitors): Industry is unlikely to be able to provide a cohesive approach to stewardship to manage the risks of the broad range of inhibitor products available, and ensure users can engage with other Government systems effectively.

MPI could support industry through the development of guidance on how to manage risks posed by the different types off inhibitors, which would increase provision of information and confidence to users. This information may not be sufficient to verify inhibitors' effectiveness and effect on the environment.

Option 3 (Changing the regulation of inhibitors): A registration under the ACVM Act would provide an approved label that provides information about the appropriate use of the product in relation to human and animal health and trade. This would help to reduce risks of misuse that may have negative impacts on other risk areas of concern, such as health and trade. Having more information about products is advantageous for regulators should there be future trade or residue issues that require a response.

The data required for ACVM assessment may also have utility for other purposes, e.g. as part of the data required for incorporation in the National Greenhouse Gas Inventory and/or Overseer.

6.5 CRITERION 5: COST EFFECTIVENESS

Option 1 (Status quo): There would be no increase in compliance costs to the manufacturers and importers of inhibitors. The potential cost of a trade disruption would continue to be borne by those parties not otherwise directly benefitting from the sale or purchase of the inhibitors.

There would be no immediate cost-impact on government, although economic and reputational risks would still be present. Economic losses may be significant should trade issues occur if inhibitor residues are detected in exported food products.

Option 2 (Industry increasing management of inhibitors):
Inhibitor manufacturers, importers, distributors, and/or sellers would need to develop stewardship information for users of inhibitors in agriculture. This may be difficult for some parts of the inhibitor industry that have limited engagement with the products, such as importers, and would present a cost. The potential cost of a trade disruption would continue to be borne by those parties not otherwise directly benefitting from the sale or purchase of the inhibitors.

Allowing the inhibitor industry to provide stewardship for their own products is more costly to industry than the status quo, but likely to be less costly to them in both time and money than direct regulatory intervention. However, economic risks would still be present (e.g. trade risks), that may be costly at a national level should they be realised and/or a response be required.

Option 3 (Changing the regulation of inhibitors): The ACVM Act is established to authorise agricultural products through the assessment of their risks to food safety, plant and animal health and trade. As a consequence of this, MPI can use this regulatory system to manage inhibitors as with other farm inputs (i.e. chemicals). This means that there would be an increased compliance cost to the registrant (both initial registration, and ongoing, including annual levies, renewal fees, and applications to change any aspect of the registration).

ACVM registration requires technical information about the product, its method of production, its safety and efficacy, and how these risks are being managed. Initial registration for each individual product costs approximately $4,000 in regulatory fees and once registered, there is an annual levy of $540 plus GST. Registration can also involve the generation of data from trials and completion of documentation, which can potentially add approximately $10,000 - $500,000 to the cost[6]. But it should be noted that a significant portion of these costs, irrespective of whether the inhibitor requires registration, would be borne by the manufacturer for product stewardship purposes.

Registration of the product may also offer some economic benefit to the company, as companies can gain data protection through the process – as the data protection granted under the ACVM Act for the registration of an innovative trade name product also triggers data protection for that product under the HSNO Act.

Information note: ACVM data protection summary

Confidential information that is used to support an application to register a trade name product (TNP) is granted data protection for 5 years, or 10 years if the product is considered an Innovative Trade Name Product (ITNP). An ITNP refers to a product containing an innovative active ingredient, which means that the active ingredient is not in any product previously registered under section 21, or a pesticide registered under the Pesticides Act 1979, or an animal remedy licensed under the Animal Remedies Act 1967.

[6] If an inhibitor is also a hazardous substance or new organism, HSNO approval is required before an ACVM registration can be granted. However, it should be noted that the HSNO Act applies to inhibitor products of this type regardless of whether they are in or out of the scope of the ACVM Act.

In addition, registered trade name products can be granted 5 years data protection for a new use or method of use.

Having data protection means that the confidential information cannot be used during the protected period to determine whether or not to grant any other TNP or innovative applications, or application to authorise a new use or method of use – unless the 'other' applicant has the consent of the party who has the protected data.

Increased regulation of inhibitor products is likely to increase user confidence in the products, and therefore their likelihood to buy, which would be commercially advantageous to the company. This option is likely to be more cost effective from a national perspective as it better manages trade and other risks, which are often costly to respond to and recover from.

What do you think?

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.
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.
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.
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?
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?
26. 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?

7 Other matters: Implementation

7.1 CHANGES TO REGULATIONS

Option 1 – Continuing with the status quo would require no legislative changes.
Option 2 – Industry would need to develop additional guidance to provide greater stewardship of their products. This may need to be supported by information from MPI to ensure that the guidance material is of sufficient and consistent quality. This would require no legislative change.
Option 3 - Changes to the ACVM legislation would be required, either through an Order in Council or amending the ACVM Act.

7.2 EFFICACY (RELEVANT TO OPTION 3, ONLY)

For any product requiring registration under the ACVM Act, the applicant generally needs to supply information to support the efficacy of the product. One of the foundations for this is to determine good agricultural practice. In many situations, the level of efficacy is based on qualitative assessment (e.g. a comparison against a known industry standard) rather than a quantitative assessment.

If inhibitors are brought within the scope of the ACVM Act, it is important to note that further expert assessment and other data requirements (e.g. usage data) are likely to be required for the product to be incorporated into the New Zealand Greenhouse Gas Inventory or Overseer.

What do you think?
Questions on efficacy Exact data requirements are outside of the scope of this discussion document. However, your feedback is sought on whether: 27. A minimum level of efficacy should be required for all inhibitor products, and if so, what this should be; 28. No minimum level of efficacy should be required, but the specific effect being claimed must have sufficient scientific evidence to support it; 29. Only specific claims should be approved (as determined by trial data, e.g. ‘reduces methane by X% on average [in XYZ conditions]); 30. Only general claims should be approved (e.g. ‘reduces methane’, rather than a specific quantitative claim); 31. 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); 32. 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.

8 Conclusion and next steps

8.1 CONCLUSION

This discussion document sets out the reasons we are undertaking a review of the approach to regulating inhibitors, and the estimated impact that each option could have on New Zealand industry and regulators. It aims to provide you with sufficient information so you can make an informed submission.

	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

Table 1. Summary of options against criteria

Based on the assessment of options against criteria (presented in matrix form in Table 1), 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.

What do you think?
Question on summary of options 33. Do you agree with the evaluation of options against criteria as presented in Table 1? If not, why not? Please provide details to support your answer.

8.2 NEXT STEPS

We are interested to hear your thoughts about whether or not New Zealand's approach to regulating inhibitors should change, and if so, how? Based on the information provided, we welcome your views in response to the questions we have asked throughout this document. Please feel free to submit other relevant information.

Once we have received submissions from interested parties, we will consider all of the new information and perspectives that have been provided. We will use this to further inform our policy analysis and further work on estimating the effects under each option. A summary of the information we have received through consultation will be made available.

Your submission may be made public – let us know if there is any information that should be withheld.

Once you make your submission, anyone can ask for it under the Official Information Act 1982 (the OIA). If you don't want anything in your submission released, you should let us know what material you want withheld, and why, at the time you make your submission. Reasons for withholding information could include that the information is commercially sensitive or that you wish personal information, such as names or contact details, to be withheld. Note that an automatic confidentiality disclaimer from your IT system will not be considered as grounds for withholding information. MPI will take your indications into account when determining whether or not to release information. The grounds for withholding information are outlined in the OIA, and we can only withhold information in accordance with those provisions. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman. Further information is available at www.legislation.govt.nz.

Appendix 1. Consolidated list of consultation questions

Questions on problem definition

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

Questions on definition of an inhibitor

5. Which of the definitions above do you prefer, and why?
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?
7. Are you aware of any definition used internationally that could be relevant to New Zealand?
8. Should the definition for an inhibitor be outcomes based? Why or why not?
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?
10. How would you define an inhibitor?
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?
13. Are you supportive of a transitional period for products requiring registration? Why or why not?
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?
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?
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.
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?
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.

Questions on criteria

19. Do you agree with the proposed criteria? Why or why not?
20. Would you propose any other criteria not covered?

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.
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.
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.

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?
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?
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?

Questions on efficacy

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

27. A minimum level of efficacy should be required for all inhibitor products, and if so, what this should be;
28. No minimum level of efficacy should be required, but the specific effect being claimed must have sufficient scientific evidence to support it;
29. Only specific claims should be approved (as determined by trial data, e.g. 'reduces methane by X% on average [in XYZ conditions]);
30. Only general claims should be approved (e.g. 'reduces methane', rather than a specific quantitative claim);
31. 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);
32. 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.

Question on summary of options

33. 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.

Please feel free to submit other relevant information.