In Confidence

Office of the Minister for Food Safety
Cabinet Economic Development Committee

Proposals to strengthen regulatory oversight of inhibitors used in agriculture

Proposal

1. This paper seeks Cabinet's agreement on proposals to change the regulatory oversight of inhibitors used in agriculture by defining them as agricultural compounds or veterinary medicines under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act).

Relation to government priorities

2. Inhibitors are important tools for our primary producers to improve environmental sustainability, including reducing greenhouse gas emissions and improving water quality. Inhibitors support the progress of the 'Action for healthy waterways' package and are a key component in the Climate Change Response (Zero Carbon) Amendment Act 2019.

Background

3. 'Inhibitors' are compounds used in agricultural production to modify certain biological and/or chemical processes in order to mitigate environmental and/or climate change impacts. Examples include a nitrogen inhibitor used in dairy farming to reduce leaching losses, or a methane inhibitor to reduce ruminant methane emissions.

4. Inhibitors are still relatively novel with a small number of products currently in the market and a limited history of use locally and abroad. They are widely considered to hold significant promise in reducing greenhouse gas emissions and nitrogen leaching into waterways.

5. Most inhibitors are currently regulated under the Hazardous Substances and New Organisms Act 1996 (HSNO). However, HSNO does not manage food safety or trade risks arising from chemical residues, animal and plant safety, dietary exposure or efficacy. These are covered by the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act).

6. Agricultural compounds as defined under the ACVM Act cover a wide range of products including animal feeds and pet food, pesticides, veterinary medicines, vertebrate toxic agents, and fertilisers, but do not specifically cover inhibitors.

The ACVM Act

7. The purpose of the ACVM Act is to prevent or manage the risks associated with the use of agricultural compounds and veterinary medicines, including risks to public health, trade in primary produce, animal welfare, and biosecurity. A further purpose of the ACVM Act is to ensure that the use of agricultural compounds do not result in breaches of domestic food residue standards.

8. The ACVM Act manages actual and potential risks from the use of chemicals in agricultural production, by providing for agricultural chemical products to be registered with MPI. Registration of these products requires a technical assessment by MPI to determine the safety of the product.

9. The ACVM Act does not specifically cover inhibitors of concern. There is still limited understanding of their effectiveness, effective and safe application (particularly in New Zealand conditions), and what if any risks they pose to food safety (e.g. through chemical residues), animal or plant safety and human dietary exposure (food safety). Among farmers, this uncertainty may result in a reluctance to invest in and use inhibitors.

10. This uncertainty may also create risks to trade, where trading partners have concerns about risks associated with the use of inhibitors in food production. An example of this occurred in 2012, when very low levels of the nitrification inhibitor dicyandiamide (DCD) were detected in processed milk. Although the level of DCD was not considered to pose a food safety risk, its detection resulted in consumer concerns and reactions from some importing countries that adversely affected dairy trade. In response, the fertiliser industry agreed to voluntarily suspend commercial sales of DCD. Sales of this product remain suspended.

Proposal to regulate inhibitors under the ACVM Act

11. I propose to strengthen the regulation of inhibitors by regulating them under the ACVM Act. This will require defining them as an agricultural compound or veterinary medicine via an Order in Council. The change will provide certainty for the primary sector and mitigate risks to trade and food safety.

12. Non-regulatory solutions would not result in sufficiently rigorous and consistent assessment of inhibitors, which is needed to provide confidence about product safety. Lack of confidence also increases risk of disruption to export trade, especially as many foreign governments will not accept non-government assurances about product safety.

13. A number of submitters indicated that, while inhibitors can offer some useful benefits in reducing emissions from ruminant animals and nitrogen leaching into waterways, uptake has been low until now. In part this is because of the lack of regulatory oversight and uncertainty about their safe use among farmers.

14. The effect of bringing inhibitors within the scope of the ACVM Act is that all of these products would have to be assessed and registered with MPI. There are a small number of inhibitors already in use with no apparent safety concerns, and some products currently registered with MPI for which suppliers might claim inhibitor effects. While these products should be assessed and registered, it is not considered necessary for them to be withdrawn from the market until this process is completed.

15. This change would bring inhibitors into line with many other products currently regulated under both HSNO and the ACVM regulations, such as pesticides.

16. I propose that inhibitors already available on the market for use in agriculture be granted a two-year transition period to lodge applications for registration with MPI, during which time they may continue to be sold. The commencement dates for this period would vary; for:

16.1 existing requirements relating to risks to human, plant and animal health – two years from commencement of the relevant regulations

16.2 efficacy requirements – two years from MPI issuing guidelines about efficacy (to be developed over a 6-12 months period).

17. Until this process is completed, there is a risk of safety concerns emerging and possibly leading to trade disruption. For these reasons, the transition should not be longer. It is also consistent with completing rigorous assessment processes.

18. MPI will provide guidance on how inhibitors will be assessed, which will be comparable to all other agricultural compounds and veterinary medicines. This will include assessing existing guidance material with regard to risks to food safety, trade, plant/animal health; and additional material relating to efficacy of inhibitors in relation to the claims being made, which will be thoroughly tested with industry before being applied.

Public consultation on options

19. Cabinet agreed to the development of a consultation document on the regulatory oversight of inhibitors used in agriculture [SUB19-0125]. From February to April 2020, MPI publicly consulted on regulatory proposals to strengthen the regulation of inhibitors including:

19.1 Option 1 – maintain the status quo – no change to how inhibitors are regulated. Involves the least compliance cost to industry and maintains current access to inhibitors.

19.2 Option 2 – increase industry management of inhibitors – a non-regulatory option. This would require those involved in selling inhibitors working with users to ensure there is sufficient information provided to manage risks to animal and plant health, food safety, and trade.

19.3 Option 3 – change the regulation of inhibitors – legal obligations would apply. Inhibitors would be identified as agricultural compounds and the risks managed by assessments under the ACVM Act.

20. MPI received 27 submissions from industry organisations, businesses and individuals (summarised in Appendix One). Submissions to the discussion paper overwhelmingly supported changing the regulation of inhibitors (option 3). Such a change would require:

20.1 defining an inhibitor as an agricultural compound or veterinary medicine under the ACVM Act;

20.2 providing a transition period to enable continued use of inhibitor products currently on the market; and

20.3 providing guidance on how inhibitors will be assessed.

21. Submissions to the discussion documents preferred the approach to defining inhibitors as substances that impact the processes of nitrification, denitrification, ammonia volatilisation, urase products or methanogenesis.

22. Section 78 of the ACVM Act requires that before recommending making an Order in Council, consultation must be undertaken with persons involved in the importation, manufacture, sale or use of the agricultural compounds or compounds that may be affected. MPI publicly consulted on the proposed changes through a discussion paper.

23. MPI also engaged with the ACVM Advisory Council (AVMAC), which consists of industry groups, producer sectors involved in the sale or use of agricultural compounds, and a consumer representative. AVMAC's purpose is to provide balanced advice to MPI on matters relating to the regulatory control of agricultural compounds and veterinary medicines. AVMAC supported the draft proposals in the draft discussion document they considered.

Financial Implications

24. There is no net fiscal impact from this proposal, as registration of products under the ACVM Act is fully cost recovered. Total costs that will be charged to suppliers seeking registration are not known as these will depend on (a) the number of products seeking registration (unknown) and (b) the time required for MPI to assess them (highly variable, but can range up to tens of thousands of dollars). There may be an initial impact on MPI having to assess many new product applications, but the amount is unknown. MPI will cover the initial impact of developing guidance and assessing new inhibitors entirely from cost recovered funds.

Legislative Implications

25. An Order in Council is required to define inhibitors as agricultural compounds, and the Parliamentary Counsel Office (PCO) will be instructed to draft this order.

26. PCO can base the drafting of the definition of inhibitors as agricultural compounds on the outcomes-based approach in the discussion document. This definition would define inhibitors as substances used to mitigate environmental, sustainability and/or climate change impacts by amending the definition of agricultural compounds to include:

- *"Any substance, mixture of substances, or biological compound, used or intended for use in the direct and/or indirect management of 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."*

Regulatory Impact Statement

27. The MPI Regulatory Impact Analysis Panel has reviewed the Regulatory Impact Statement '*Strengthening the regulation of inhibitors used in agriculture*' produced by MPI and dated 15 July 2020. The review team considers that it meets the quality assurance criteria.

28. The review team notes that the evidence presented on the nature and size of the problem is limited, which raises uncertainty about the need for the proposed regulation of inhibitors. However, the Impact Statement clearly identifies significant risks with non-regulation, or with industry stewardship alone, including risks to human, animal and plant health and to trade disruption, as well as identifying benefits, such as better environmental outcomes. There was also almost full support for the preferred option from submitters on the discussion document. Overall we are satisfied that the proposed preferred option is appropriate to address the stated problem.

29. The Regulatory Impact Statement is attached as Appendix Two.

Climate Implications of Policy Assessment

30. The Ministry for the Environment has been consulted and confirms that the Climate Implications of Policy Assessment (CIPA) requirements do not apply to this proposal as the emissions impact is unable to be quantified due to insufficient activity and efficacy data.

31. The impact of this proposal on net emissions is uncertain. However, this proposal will potentially support future consideration of emissions from the agriculture sector by regulating inhibitor chemicals used in agriculture that mitigate climate change impacts. The regulatory change proposed will likely help to develop a stronger evidence base of the emissions impact of these types of products as the efficacy of these products will be assessed as part of a registration process. The Ministry for the Environment expects that greenhouse gas analysis will be carried out once this data is available. The climate impacts of this regulatory change are likely, in time, to be reflected in New Zealand's Greenhouse Gas Inventory.

Population Implications

32. There are no impacts on specific population groups from this proposal.

Human Rights

33. There are no implications under the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993.

Departmental Consultation

34. The following government departments were consulted in the development of this paper: Ministry for the Environment (Environment); Environmental Protection Agency (Environment); The Treasury (Finance); Te Puni Kōkiri (Maori Development); Ministry of Business, Innovation and Employment (MBIE); Ministry of Foreign Affairs and Trade (MFAT); and the Department of the Prime Minister and Cabinet.

Communications

35. MPI will provide guidance to applicants regarding the data requirements for registering inhibitors, which will be comparable to existing requirements for all other agricultural compounds that must be registered.

36. A summary of submissions to the discussion paper has been prepared (Appendix One) and will be published on MPI's website.

37. I intended to release a media statement following Cabinet decisions. This will provide the primary sector and public with certainty on the direction of travel.

Proactive Release

38. 30 days following Cabinet consideration, I intend to proactively release this paper and the Regulatory Impact Statement in full.

Appendix One: Summary of submissions

A discussion document outlining options for regulation of inhibitors was published by MPI in February 2020 (see https://www.mpi.govt.nz/news-and-resources/consultations/the-regulation-of-inhibitors-used-in-agriculture/), with submissions closing in April 2020.

There were twenty-seven submissions received (plus one informal response which did not address the questions in the discussion document). Submitters represented:

- primary producers, processors and exporters
- fertiliser and agricultural chemical suppliers
- industry organisations representing the above businesses
- public sector entities engaged in agricultural research, animal welfare and environmental policy.

Submitters generally supported increased regulatory oversight

All except one submitter, from across the spectrum of stakeholder interests, agreed with MPI's proposal that inhibitors should be brought within the ambit of the ACVM Act 1999 by classifying them as 'agricultural compounds'. They stated that the current lack of regulatory oversight results in reputational risks for exports, and that uncertainty about safety and efficacy may discourage use of inhibitor products. The DCD incident was frequently cited as an example of the risks arising from lack of regulation of inhibitors.

There was however a diversity of views on the detail of regulation, on matters such as the definition of inhibitors, transitional provisions and legal requirements re product efficacy.

An outcomes-based or prescriptive definition?

There was a general preference for a definition of inhibitors that focuses on outcomes such products will deliver, rather than a more prescriptive one specifying chemical processes that they would modify. A number of submitters stated that MPI's proposed definition is too general; and several suggested calling these products 'environmental impact mitigators'.

How long for a transition period?

The main concern about the transition to a new regime is how inhibitors already in use should be treated; whether they should be allowed a transitional period of two years to gain registration, during which time they could continue to be used (MPI's proposal); or whether a longer period would be required, with a number of submitters proposing a transitional period of up to five years.

Submitters see a need for scientific evidence of efficacy

There was a wide variety of views about whether there should be legal requirements for MPI to verify the efficacy of inhibitors, i.e. the environmental effects claimed by suppliers (in addition to MPI assessing risks to plant/animal/human health).

The majority view was that there should not be a minimum level of efficacy required for inhibitor products, given the wide range of potential effects which cannot be easily reflected in a single standard. However, among both those submitters that supported and opposed a minimum level, there was agreement that products should be required to validate claimed benefits with scientific evidence.

Recommendations

The Minister for Food Safety recommends that the Committee:

1. **Note** that the current regulatory framework for inhibitors under the Hazardous Substances and New Organisms Act 1996 does not adequately manage risks to trade from residues, human and animal safety, dietary exposure or efficacy;

2. **Note** that public consultation was undertaken between February and April 2020 on proposed changes to strengthen the regulation of inhibitors used in agriculture and almost all submissions supported regulation under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act);

3. **Agree** to strengthen the regulation of inhibitors used in agriculture by defining inhibitors used in agriculture as agricultural compounds or veterinary medicines, causing them to be regulated under the ACVM Act;

4. **Authorise** the Minister for Food Safety to issue drafting instructions to the Parliamentary Council Office for an Order in Council to implement the above policy decision;

5. **Agree** to release an exposure draft of the amended ACVM Regulations to the ACVM Advisory Council (AVMAC) to satisfy the consultation requirements (of the Act) for an Order in Council;

6. **Authorise** the Minister for Food Safety to make final decisions on minor and technical issues and make changes consistent with the policy intent described in this paper on any issues that arise during the drafting process.

Authorised for lodgement

Hon Dr Ayesha Verrall
Minister for Food Safety

Coversheet: Strengthening the regulation of inhibitors used in agriculture

Advising agency	Ministry for Primary Industries
Decision sought	Agree that an Order in Council be drafted to define inhibitors used in agriculture as agricultural compounds or veterinary medicines
Proposing Minister	Minister for Food Safety

Summary: Problem and Proposed Approach

Problem Definition

What problem or opportunity does this proposal seek to address? Why is Government intervention required?

'Inhibitors' are compounds used in agricultural production to modify certain biological and/or chemical processes in order to mitigate environmental, sustainability and/or climate change impacts.

There is limited regulatory oversight over inhibitors, and this has resulted in a level of uncertainty among suppliers and farmers that has reduced usage of these compounds. The limited regulatory oversight also poses risks to New Zealand's reputation and trade.

A discussion document outlining options for regulation of inhibitors was published by MPI in February 2020 (see https://www.mpi.govt.nz/news-and-resources/consultations/the-regulation-of-inhibitors-used-in-agriculture/), with submissions closing in April 2020. Feedback was received from businesses and industry organisations representing farmers, suppliers of inhibitors and other interested parties.

Summary of Preferred Option

MPI proposes that inhibitors should be brought within the remit of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 by classifying them as 'agricultural compounds'. This would require these products to be registered for use, as part of which any risks associated with them (such as to the safety of animals or plants, and any chemical residues in food derived from them) would have to be explicitly considered in line with the Act's objectives and processes. This would in turn would provide foreign governments with confidence that they are used safely in New Zealand, in order to minimise any risk of disruption to trade.

This approach would also require suppliers to demonstrate that the products would deliver the environmental benefits claimed (with scientific evidence specific to New Zealand).

This option is considered preferable to non-regulatory solutions as it provides robust assessment of risks to human, animal and plant health (using existing ACVM methodologies); clear and consistent information about safe and effective use; and significantly lower likelihood of trade disruption. While the proposed regulation would result in higher costs to suppliers and uses of these products, there costs are considered to be outweighed by the above benefits.

It is also expected that the proposed regulatory process would provide farmers with confidence that the products can be used properly and safely. This would result in greater uptake, with benefits including reduced emissions and nitrogen leaching into waterways Almost all submitters responding to the discussion document agreed with this option.

This approach is consistent with the recommendations in the Cabinet paper.

Section B: Summary Impacts: Benefits and costs

Who are the main expected beneficiaries and what is the nature of the expected benefit?

The main beneficiaries of the proposed regulation of inhibitors are primary producers who face reduced risks of trade disruption associated with unregulated use.

It is also expected that the proposed regulation of inhibitors will lead to more confidence in them and more widespread use, with benefits in reduced carbon emissions and less nutrient leaching to waterways.

However, the size of the current trade risk, the potential uptake of inhibitors under the regulated regime, and the extent to which regulation will reduce trade risk cannot be estimated.

Where do the costs fall?

There are significant up-front costs of generating and assessing evidence of the impacts of inhibitor needed to secure regulatory approval, along with minor ongoing regulatory costs.

These costs will initially be met by suppliers of inhibitor products; however, as supply is on a commercial basis, costs will to a greater or lesser extent be passed on to users.

What are the likely risks and unintended impacts? How significant are they and how will they be minimised or mitigated?

There were two implementation issues identified through consultation:

- MPI's capacity to assess scientific evidence about the safety of inhibitor products; and
- compliance costs to suppliers (for both generating evidence and for MPI to assess it); if these costs are too high, they could become a barrier to adoption of inhibitors.

We consider that the number of potential applications for registration of inhibitor products is likely to be small relative to the total number of applications for new and amended registrations (2,600 annually); so do not expect MPI capacity to be challenged under the proposed regime.

Compliance costs are inevitably a risk of this system, but MPI will attempt to avoid unnecessary compliance costs for inhibitors through: relying on data already provided to other governments wherever possible; using existing guidance material with regard to risks such as public health, animal or plant health, residue management and trade in primary produce; and thoroughly testing guidance material relating to efficacy with industry before being applied.

There is also a possibility that some "low risk" inhibitors might be required to go through a (costly) full registration process. However, specific products can be exempt from this providing they meet certain conditions set out in the ACVM exemptions regulations.

Section C: Evidence certainty and quality assurance

Agency rating of evidence certainty?

We have limited information about the current and potential use of inhibitors, the risk of trade disruption they pose, and the impact of regulation on their potential use. Specifically:

- inhibitor products are relatively novel, so the risks they pose are uncertain (especially in New Zealand conditions); however, under the proposed regulatory regime the onus is on suppliers to generate information on these matters, and there are well-developed methodologies for assessing this information
- given this novelty, the claimed benefits of inhibitors (reduced emissions, nitrogen leaching) have also yet to be established, although initial evidence suggests some promise
- MPI is aware of a small number of inhibitors currently available in New Zealand, and that there are others under development; there may also be some existing ACVM products whose suppliers might claim inhibitor properties; however, given the novelty of the products and normal commercial sensitivities of their suppliers, the potential size of the market is unknown
- the likely uptake of inhibitors in the current (unregulated) market and under the proposed regulatory regime is highly speculative
- the types of trade disruption events of concern – where a trading partner threatens to restrict access to a New Zealand product because an inhibitor has been used in its production (with or without scientific justification) – are rare and the potential impact is dependent on the size of the market at risk; so there is no robust way to estimate the potential costs of trade disruption.
  There is one instance of this in 2012 relating to an inhibitor, which MPI was able to resolve without loss of market access; however the product in question was withdrawn from sale and has not subsequently been offered in the local market. MPI has also had to address trade disruption events from other causes, on the basis that the potential costs in lost exports are can tun into millions of dollars.

While the available evidence is limited, we are confident that the proposed solution is consistent with MPI's general approach to regulation of food safety, animal and plant health and export trade.

Quality Assurance Reviewing Agency:

Ministry for Primary Industries

Quality Assurance Assessment:

The MPI Regulatory Impact Analysis Panel has reviewed the Regulatory Impact Statement 'Strengthening the regulation of inhibitors used in agriculture' produced by MPI and dated 15 July 2020. The review team considers that it **meets** the quality assurance criteria.

Reviewer Comments and Recommendations:
The review team notes that the evidence presented on the nature and size of the problem is limited, which raises uncertainty about the need for the proposed regulation of inhibitors. However, the Statement clearly identifies significant risks with non-regulation, or with industry stewardship alone, including risks to human, animal and plant health and to trade disruption, as well as identifying benefits such as better environmental outcomes. There was also almost full support for the preferred option from submitters on the discussion document. Overall, we are satisfied that the proposed preferred option is appropriate to address the stated problem.

Impact Statement: Strengthening the regulation of inhibitors used in agriculture

Section 1: General information

1.1 Purpose

The Ministry for Primary Industries is solely responsible for the analysis and advice set out in this Regulatory Impact Statement, except as otherwise explicitly indicated.

This analysis and advice has been produced for the purpose of informing final decisions to proceed with a policy change to be taken by the Cabinet.

1.2 Key Limitations or Constraints on Analysis

The following were ruled out of scope in the consultation document

- exactly how inhibitors would be managed if regulated under legislation
- management of chemical residues if inhibitors are regulated as agricultural compounds
- proposals to amend *Codex Alimentarius*
- proposals to amend the Hazardous Substance and New Organisms (HSNO) Act 1996
- proposals to amend the New Zealand Agricultural Greenhouse Gas Inventory methodology
- how inhibitors should be incorporated in *Overseer* or any other models.

There is limited evidence of the scale of the problem, in terms of both current and potential use of inhibitors, risks of trade disruption and the impact of regulation on the market for inhibitors. However, there is one instance of trade disruption from the use of inhibitors (DCD in 2012 – see below) which confirms the possibility and impacts of the risks.

(See Section C in the Summary for a full discussion of evidence limitations.)

1.3 Responsible Manager (signature and date):

Naomi Parker

Acting Director, Food and Regulatory Policy

Policy and Trade Ministry for Primary Industries (MPI)

/ /2020

Section 2: Problem definition and objectives

2.1 What is the current state within which action is proposed?

Agricultural compounds used in New Zealand are subject to the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. The information box below summarises aspects of the ACVM system relevant to this analysis.

Many New Zealand farmers are looking for ways to reduce nutrient losses to waterways and greenhouse gas emissions from ruminant animals, as a result of regulation (eg freshwater reforms, Emissions Trading Scheme), consumer demands and trading partner requirements. One potential set of tools is the use of 'inhibitors' in agricultural production - compounds that can be applied through, eg, fertilisers or animal feed supplements to modify certain chemical and/or biological processes, in order to mitigate environmental, sustainability and/or climate change impacts.

Inhibitor products might include entirely new compounds, existing products with additional ingredients, or existing products where research has generated evidence of inhibitor effects.

These are relatively novel products which have only been developed and marketed globally over the last 10-15 years in response to concerns about environment and climate change. There are already inhibitor products available in the New Zealand market, and more are being developed locally and abroad. The consultation process disclosed a small number of products currently on sale and in development in New Zealand. However, this is likely to be an understatement of the size of the market.

While the underlying science to develop inhibitors is generally done abroad, there is usually a significant amount of local research needed to incorporate them in products that can be used safely and effectively in New Zealand.

The Biological Emissions Reduction Group (BERG 2018)[1] commissioned an analysis of different mitigation technologies from the New Zealand Agricultural Greenhous Gas Centre. It suggested that the mitigation options with the greatest potential for reducing agricultural greenhouse gas emissions include methane inhibitors and vaccines, nitrification inhibitors and genetically modified ryegrass. However, these are not yet commercially available, although some have proof of concept (eg a methane inhibitor for feedlot animals) or proven benefits (eg nitrification inhibitors).

It also noted that mitigation options reducing nitrous oxide emissions have significant co-benefits to water quality and nutrient discharges.

The pressures on the agricultural sector to improve water quality and reduce climate change impacts should result in increased demand for inhibitor products; however, uptake of inhibitors to date has been modest. There are some factors currently limiting the availability of products. Anecdotally we understand that some suppliers are currently not offering inhibitors for sale due to the potential risks to trade, or until a change in regulation provides data protection for these products vis-à-vis other comparable products (see information box below).

While we are aware of some research into inhibitor products, the potential scale of this is unknown as (a) this information is usually closely held until products come to market and

[1] **Biological Emissions Reduction Group (BERG)** *Report*, December 2018 https://www.mpi.govt.nz/dmsdocument/32125/direct

(b) the willingness of suppliers to release products into the market depends in part of the regulatory rules governing them. Berg (*op.cit*) indicated high confidence that a methane inhibitor would be available for in-shed feeding by 2020, but noted that this depends in part on whether it would be subject to the ACVM and HSNO Acts.

The ACVM system: key points

Agricultural compounds coming within the scope of the ACVM Act must generally be registered as Trade Name Products (TNPs) before they can be imported, manufactured, sold or used. Registration requires MPI to undertake a technical assessment (drawing on scientific evidence provided by the applicant) to determine the level of risk such as public health, animal or plant health, residue management and trade in primary produce, and how this will be managed.

The total size of the New Zealand market for ACVM products (at wholesale level) was estimated by NZIER (2019)[2] as:

- agricultural chemicals: $350 million
- veterinary medicines: $370-410 million.

As of 30 June 2020 there were 361 businesses holding 3,484 registered TNPs. On average, approximately 2,600 applications for new TNPs and modifications to existing registrations were received annually from 2010 to 2017. There is a trend for a gradual increase in the number of applications year on year.

MPI exempts some classes of low-risk ACVM products (eg fertilisers) from registration.

MPI does not examine products' toxicology or environmental impact; if necessary, this is assessed by the Environmental Protection Agency (EPA) under the HSNO Act. Where HSNO approval is required, MPI may not register a product until that approval is granted.

As part of the approval process, MPI allows data generated overseas from applicants which has already been provided to overseas regulators, which reduce the applicant's costs. However, it generally needs data from New Zealand field trials to establish the safety of animals or plants, any chemical residues in food derived from them and efficacy (see below) under New Zealand conditions. Costs of generating this data were estimated to range from $10,000 to $500,000 per TNP in 2008 (COVEC 2009[3]), and may take several years, depending on the amount of trial work required, or challenges in producing data where field conditions are not conducive.

To meet regulatory timeframes under the Act, MPI requires applicants to utilise third-party data assessors to verify the robustness of the data in applications. This allows MPI to focus on risk assessment and management. Its costs for technical assessment and registration may run to tens of thousands of dollars. These and ongoing costs of operating the regulatory system (which are relatively minor) are fully recovered from registrants.

2 **New Zealand Institute of Economic Research (NZIER)** (2019) *Costs of patent extension and further data protection* report to the Ministry for Primary Industries, December 2019

3 **COVEC** (2009) *Data Protection for Agricultural Compounds and Veterinary Medicines* report to the New Zealand Food Safety Authority, February 2009

Incurring costs to develop the necessary information to support registration applications is a commercial decision by the supplier of the product, on the basis that these costs will be offset by profits from sales after gaining access to the market. MPI is required under the ACVM Act to hold proprietary information supplied as part of an application for an 'innovative' product or 'innovative' use of an existing product for 5-10 years, and to not use it for any other application. This restriction operates as a form of intellectual property protection (NZIER 2019), allowing the applicant to defray the costs of generating the information through sales of the product over the duration of the data protection period. If a different producer wishes MPI to use the proprietary information in support of its own application, it would have to wait until the data protection expires (or make commercial arrangements for access with the original owner).

The Act does not explicitly require MPI to confirm the efficacy of TNPs nor the accuracy of product claims. However, any use of an ACVM product may pose a risk to the plant or animal to which it is administered, and/or create a perception of risk that might affect trade; MPI is reluctant to register products that generate risk if there is no demonstrable benefit.

Moreover, under good agricultural practice, products should be applied at the lowest dosage that has the intended effect, which necessarily involves consideration of efficacy. This is reflected in the approval of each TMP's label, which must stipulate how it is to be used safely and appropriately.

Benefits claimed by suppliers would also subject to Fair Trading Act provisions, although the Commerce Commission (which administers that Act) may lack the scientific expertise to evaluate the truthfulness of ACVM product claims.

2.2 What regulatory system(s) are already in place?

Relevant legislation includes:

- the Hazardous Substances and New Organisms (HSNO) Act 1996
- the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997
- the Animal Products Act (APA) 1999.

The purpose of the HSNO Act 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. It is administered by the Environmental Protection Agency (EPA). This Act is the only legislation that directly covers inhibitors; however, it does not manage the risks identified in S2.1.

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).

The APA regulates the export of animal products and materials; chemical residues in these commodities are managed to ensure compliance with importing country requirements. However, domestic chemical residue regulation does not necessarily provide assurance for exports, but it can help.

The use of inhibitors in agricultural production is not directly regulated under any Act, leaving a regulatory gap in relation to management of the risks identified in section 2.3 above.

The question of whether Government regulation would be preferable to non-regulatory solutions was tested in consultation, and is discussed in the analysis of options (section 4).

The use of inhibitors may support better outcomes in the following areas (and these reforms may in turn incentivise the use of inhibitors):

- 'Action for healthy waterways' – in particular, reducing nitrogen leaching into waterways
- climate change - in particular, reduced methane emissions.

2.3 What is the policy problem or opportunity?

Inhibitors are still relatively novel, with a relatively small number of products currently in the market, and a limited history of use. There are also new products being developed locally and abroad, and some existing products that may have inhibitor properties.

Inhibitors are seen to hold significant promise in reducing greenhouse gas emissions and nitrogen leaching into waterways (BERG 2018).

Like any ACVM product, inhibitors may result in risks to the animals or plants to which they are applied (including places where animals or plants are located), and to human health (eg through chemical residues) and dietary exposure (food safety). However, under existing ACVM regulatory processes, the onus is on suppliers to generate information about these risks; and MPI has well-developed methodologies for assessing the information and determining whether impacts are within safe limits.

There is a greater level of uncertainty about how effective inhibitors are in delivering claimed benefits; and how they should be applied to be effective and safe, particularly in New Zealand conditions.

This limited understanding is not just a New Zealand phenomenon. It is the norm in other jurisdictions, along with limited regulatory oversight.

Among farmers, this uncertainty may result in a reluctance to invest in inhibitors.

This uncertainty may also create risks to trade, if trading partners are concerned about risks associated with inhibitors' use in food production – both 'underlying' risks and risks resulting from 'inappropriate' application. There are no international standards governing the use of inhibitors, nor have any trading partners incorporated restrictions or limits relating to them in market access requirements. Perversely, the absence of explicit standards may create a risk of trade disruption, if another country decides to take unilateral action against foods where inhibitors had been used in production.

An example of the impact of these risks occurred in 2012, when very low levels of the nitrification inhibitor dicyandiamide (DCD) were detected in milk.[4,5] Although DCD was not considered to pose a food safety risk, this detection resulted in consumer concerns and reactions from some importing countries that adversely affected trade. In response, the fertiliser industry agreed to voluntarily suspend commercial sales of DCD, and sales of this product remain suspended.

4 See http://www.stuff.co.nz/the-press/8219131/Blow-to-dairying-and-environment

5 This product is used worldwide, and was included in fertilizers registered under the ACVM Act, which were marketed as having both fertiliser and inhibitor properties.

There have also been instances where trading partners have expressed concerns about other exported food products (not necessarily with robust scientific justification or vis-a-vis international food standards). These led to threats of loss of market access; and while MPI was able to resolve the problems and prevent this happening, it had to use significant resources to do so.

While these problems were triggered by one exporter's actions with regard to a particular product, the response from the other country frequently extended more widely – for example, to all New Zealand exports of the product in question. Such situations typically put trade in the order of millions of dollars at risk.

These events have generally occurred in situations of little or no regulation of the exported product, and reinforce this assessment of the risks resulting from light-handed regulation. .

In some instances, trading partners' concerns are transmitted back to exporters and food processors, who may be reluctant to process inputs where inhibitors have been used in production, or place unnecessarily stringent requirements on such inputs. Some industry organisations have also said that they have been asked to provide advice to their members on the use of inhibitors (without necessarily having the scientific expertise to do so). In effect, the exporters and industry organisations can become *de facto* regulators; but during consultation emphatically stated that they did not see this as their role.

In normal market settings these problems would be addressed through suppliers investing in the development of markets for inhibitor products, by building a robust evidence base about the value and safety of the products. In time this would result in users being confident in their effectiveness and knowledgeable in how to apply them properly; and others in the supply chain (up to and including trading partners) understanding the risks associated with their use and how these risks are being mitigated.

Given the novelty of inhibitor products, we cannot estimate what a likely trajectory would look like (in terms of products or speed of uptake) in the absence of regulation.

However, we conclude that on the balance of probabilities, it is likely that the uptake of inhibitors will be slower, and the risks of trade disruption heightened, in the absence of suitable regulation.

This view is shared by industry – see next section. .

2.4 What do stakeholders think about the problem?

Stakeholders include:

- primary producers that might use inhibitors (eg sheep, beef, dairy farmers, vegetable growers)
- primary producers that might be affected by others' use of inhibitors (eg beekeepers, horticultural producers)
- processors and exporters of primary products – the latter are exposed to trade-related risks arising from inhibitors
- suppliers of inhibitors, including fertiliser and agri-chemical companies
- industry organisations representing the above businesses

- public sector entities engaged in agricultural research and animal welfare.

25 individuals and organisations made submissions in response to the discussion document.

Almost all submitters, from across the spectrum of stakeholder interests, shared MPI's views about the nature of the problem and the preferred solution. A number reinforced the arguments for the preferred solution with information about their own experience in the current regulatory environment; in particular, the DCD incident was frequently cited as an example of the risks arising from limited regulation of inhibitors.

Only one submitter (a potential manufacturer of inhibitors) did not agree with the preferred solution. It indicated concerns about the impact of overly burdensome or distortionary regulation, and consequences such as discouraging use of inhibitors (with poorer environmental and trade outcomes) and incentivising offshore production of inhibitors. It stated a preference for the industry stewardship option.

There was however a diversity of views on the detail of regulation:

- There was a general preference for a *definition* of inhibitors that focuses on outcomes such products will deliver, rather than a more prescriptive one specifying chemical processes that they would modify. A number of submitters stated that MPI's proposed definition is too general; and several suggested calling these products 'environmental impact mitigators'.
- The main concern about the *transition* to a new regime is how inhibitors already in use should be treated; whether they should be allowed a transitional period of two years to gain registration, during which time they could continue to be used (MPI's proposal); or whether a longer period would be required, with a number of submitters proposing a transitional period of up to five years.
- There was a wide variety of views about whether there should be legal requirements for MPI to verify the *efficacy* of inhibitors, ie the environmental effects claimed by suppliers (in addition to MPI assessing risks to plant/animal/human health).

  The majority view was that there should not be a minimum level of efficacy required for inhibitor products, given the wide range of potential effects which cannot be easily reflected in a single standard. However, among both those submitters that supported and opposed a minimum level, there was agreement that products should be required to validate claimed benefits with scientific evidence.

2.5 What are the objectives sought in relation to the identified problem?

Based on the problem definition in section 2.3 above, the key objectives are

1. Risk management

- affected parties understand the risks associated with inhibitors and how to manage these risks – including risks to plant and animal health, food safety and trade

2. ***Information***

- users have sufficient information about inhibitors to use them confidently and effectively

In addition, as the use of inhibitors is essentially a commercial decision by famers and suppliers, it is necessary to include a third objective -

3. Cost effectiveness

- any costs imposed on users and suppliers of inhibitors should be no more than is necessary to achieve intended outcomes, and proportionate to benefits.

These objectives are reflected in the evaluation criteria in section 3.2 below (with 'risk management' split into three criteria according to different dimensions of risk).

A preliminary assessment suggests that the first two objectives are broadly consistent – that is, an improvement in either (or any dimension of either) is generally associated with an improvement (or no negative impact) in the other – but the key trade-off is between these two objectives and the potential costs imposed.

That said, any increase in risk (especially trade risk) could potentially lead to major costs to users if the risks were realised, and trade disrupted and/or major remedial actions (eg product recalls) required.

Section 3: Option identification

3.1 What options are available to address the problem?

Two alternatives to the status quo were presented for consultation

- **increased industry stewardship of inhibitors** - a non-regulatory option which would require those involved in selling inhibitors to work with users to ensure there is sufficient information provided to manage risks to animal and plant health
- **changing the regulation of inhibitors**, with these products classified as 'agricultural compounds', and the risks managed through assessment under the ACVM Act.

The key implication of changing the regulation of inhibitors is that products identified as agricultural compounds would have to be registered as Trade Name Products (TNPs) under the ACVM Act.

The effectiveness of each s vis-à-vis the objectives is discussed in more detail in the analysis of options (section 4). However, this can be broadly characterised as follows:

- the industry stewardship option is low cost and would have few barriers to relatively quick uptake of inhibitors; but we cannot be confident that this model will manage the risks posed by inhibitors
- the regulatory option should enable risks to be managed effectively, and is probably better at addressing the informational barriers to uptake of inhibitors (depending on decisions about efficacy – below); but assessment processes required will impose additional time requirements and significantly higher costs.

These options are mutually exclusive. No additional options were identified through consultation.

Within the second option, regulation of inhibitors, there are important sub-options relating to appropriate rules for a new system:

- how inhibitors already in use should be treated[#]; should they be
    - exempted from registration requirements?
    - allowed a transitional period of two years to gain registration, during which time they could continue to be used?
    - allowed a transitional period of up to five years?

([#] assuming all products introduced to the market after regulations come into force would need to be registered or exempted.)

- what if any requirements there should be for MPI to verify the efficacy of inhibitors (ie the environmental effects claimed by suppliers), in addition to assessing risks to plant/animal/human health; whether:
    - a minimum level of efficacy should be required for all inhibitor products, and if so, what this should be
    - no minimum level of efficacy should be required, but the specific effect being claimed must have sufficient scientific evidence to support it
    - only specific claims should be approved (as determined by trial data, e.g. 'reduces methane by X% on average [in XYZ conditions])

- only general claims should be approved (e.g. 'reduces methane', rather than a specific quantitative claim)
- 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%; with the level a product could claim determined by the trial data)
- alternative options should be considered for efficacy requirements, or other matters should be taken into consideration.

(As noted above, alternative terminology and definitions of inhibitors were also tested during consultation. These are considered to be of a technical nature and do not require separate analysis.)

3.2 What criteria, in addition to monetary costs and benefits have been used to assess the likely impacts of the options under consideration?

The following criteria were used for the evaluation of options in the consultation document:

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 that users of inhibitors in agriculture need to use them safely?
   - Will the intervention provide the information that 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?

3.3 What other options have been ruled out of scope, or not considered, and why?

The following were ruled out of scope for consultation:

- 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 chemical residues if inhibitors are regulated as agricultural compounds; this is normally done through Maximum Residue Levels (MRLs), which are regulated under the Food Act 2014
- proposals to amend *Codex Alimentarius*, as this review is focused on the regulation of inhibitors in New Zealand

  (The *Codex Alimentarius* is the collection of food standards and related texts adopted by the Codex Alimentarius Commission of the Food & Agriculture Organisation and the World Health Organisation. These standards have been established to protect the health of consumers and to ensure fair practices in the global food trade.)
- proposals to amend the 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 regimes regulating substances and biological compounds in New Zealand
- how inhibitors should be incorporated in *OverseerFM* (determined by Overseer Ltd) or any other models.

  (*OverseerFM* is proprietary software that analyses the flow of nutrients through individual farms, and produces nutrient budgets for seven key farm nutrients, as well as greenhouse gas reports.)

Section 4: Impact Analysis

Marginal impact: How does each of the options identified in section 3.1 compare with taking no action under each of the criteria set out in section 3.2?

Main options

	No action	Increased industry stewardship of inhibitors	Changing the regulation of inhibitors
1. Manages risks to plant and animal health	0	+	++
2. Manages risk to food safety	0	+	++
3. Manages risk to trade	0	0	++
4. Provides information and confidence to users and policy agencies	0	+	++
5. Cost effectiveness	0	-	++
Overall assessment	0	+	++

Key:

++	much better than doing nothing/the status quo
+	better than doing nothing/the status quo
0	about the same as doing nothing/the status quo
-	worse than doing nothing/the status quo
- -	much worse than doing nothing/the status quo
?	uncertain/ unknown

For the first two criteria - **managing risks to plant and animal health and to foods safety** – the regulatory solution is clearly more effective, as this is what the legal framework is explicitly designed to manage. The risk assessment required as part of the regulatory regime is reinforced by (a) sanctions for non-compliance and (b) mechanisms for Government to intervene if problems occur (eg mandating product recalls). The 'industry stewardship' would represent an improvement over the 'no action' scenario, but is less effective than regulation because of potential inconsistency in how different suppliers apply stewardship requirements, and lack of sanctions and mechanisms for breaches.

The industry stewardship option is also likely to be less effective in dealing with **trade risk.** This risk is generally managed through government-to-government agreements, and MPI's experience is that foreign governments are more likely to accept government assurances based on a regulated system than private arrangements and undertakings.

Issues relating to the **information** criterion are discussed below.

The regulatory solution is unambiguously more **expensive** than the stewardship one; the level of evidence required by MPI and the costs of generating it will be at least as great as suppliers would produce themselves and probably much higher. These costs can range from tens to hundreds of thousands of dollars per product, especially if local field trials are required.

However, we consider that the regulatory option is likely to be preferred from a **cost-benefit** perspective. The stewardship option is assessed as less effective in managing risk, and therefore more likely to result in trade disruption, which has potentially significant costs to industry. Many of these costs might be imposed on producers that do not use inhibitor products that generate the trade risk– for example, affecting an entire category of exports rather than just those where a 'problematic' inhibitor has been used.

While we cannot quantify this cost because of uncertainty over probability and scale of any negative trade disruption, our experience is that such disruptions can easily generate millions of dollars of costs to local industry. The cost of the DCD event to New Zealand's food safety reputation was significant, although hard to measure.

Sub-option 1 (within regulatory option) –transitional arrangements for existing products

	No action	Existing products exempt	Two year transitional period	Five year transitional period
1. Manages risks to plant and animal health	0	0	++	+
2. Manages risk to food safety	0	0	++	+
3. Manages risk to trade	0	0	++	+
4. Provides information and confidence to users and policy agencies	0	0	?	?
5. Cost effectiveness	0	0	?	?
Overall assessment	0	0	++	+

Exempting existing products offers no improvement vis-à-vis the current situation, as they are currently unregulated. As such, it does nothing to manage the potential health and trade risk; and perversely, precludes the examination of the products to determine whether they pose any risks. Either transitional period would represent an improvement.

The two year transition period was proposed in consultation, on the basis that products currently in use that are not presenting obvious problems should continue to be available; but standard ACVM processes for registration should be undertaken to confirm safety and ensure neutral treatment vis-a-vis new products. MPI explicitly stated that there would be no 'grandfathering' (ie automatic registration) of existing products, and this position was not challenged by submitters.

The main issue of contention was the length of any transition period, given the requirements for suppliers to compiling scientific data about risks, and MPI to evaluate it. There is some uncertainty about what evidence would be required, and therefore whether two years would be sufficient. A specific concern is if field trials are required to demonstrate appropriate use in New Zealand conditions, a two year period would be inadequate as this would enable only one or possibly two seasons' data to be generated. For this reason, a number of submitters sought a longer transition period, of up to five years.

As a corollary, a longer transition period is likely to pose higher risks than a two year period, as any risks to plant or animal health, or food safety will take longer to identify, and the possibility that perceptions of risk could disrupt trade will be present for a longer period.

The main uncertainty is whether two years would be long enough, in terms of the number of current products seeking registration (number unknown but likely to be small), the time required to generate and compile information for an application, and MPI's capacity to assess this information. If there are problems in this regard, it could lead to less confidence, additional costs and/or lower uptake of inhibitors.

As noted previously, potential inhibitors fall into two categories:

- products that are already registered as TNPs, for which claims about inhibitor properties might now be made
- inhibitor products already in the market not registered as TNPs.

There are two aspects of transition for these products:

- requirements for product efficacy (see next section) – it is assumed that products will be subject to existing requirements re animal and plant health and food safety, and will have already demonstrated this (existing TNPs) or can do so (inhibitor products already in the market)
- whether the transition period should relate to the time required to register a TNP, or to generate data and submit an application for registration

After reviewing the submissions, MPI has concluded that

- two years will be sufficient, and a longer transition generates unnecessary risks
- the focus should be on the application timeline, as this is what is what applicants can control; registration includes MPI's assessment times
- the transition period should be split between
    - existing requirements not related to efficacy – two years from commencement of the relevant regulations to lodging an application to (a) add an efficacy claim on an existing TNP product label, or (b) secure registration for an existing non-TNP inhibitor
    - efficacy requirements - two years(#) from MPI issuing guidelines about efficacy for both types of applicants to lodge an application in respect of this.
      (# expected to take 6-12 months from commencement of the regulations)

Sub-option 2 (within regulatory option) – efficacy requirements

	No action	A minimum level of efficacy	No minimum level of efficacy (but sufficient scientific evidence to support the specific effect being claimed)	Only specific claims should be approved (as determined by trial data)	Only general claims should be approved	Only graduated levels of general efficacy claim should be allowed on the label
1. Manages risks to plant and animal health	0	0	0	0	0	0
2. Manages risk to food safety	0	0	0	0	0	0
3. Manages risk to trade	0	0	0	0	0	0
4. Provides information and confidence to users and policy agencies	0	++	+	++	+	+
5. Cost effectiveness	0	- -	-	- -	-	-
Overall assessment	0	?	?	?	?	?

The issue of whether, as part of the registration process, MPI should require and review evidence about efficacy was raised on the basis that the novelty of products means that additional scrutiny is required. The options are effectively 'in principle' trade-offs between benefits to users of better information about efficacy and the costs of generating scientific evidence to support this.

As noted previously, current MPI practice is to scrutinize suppliers' efficacy claims in order to establish some positive effects (supported by scientific evidence); as MPI is reluctant to register products that generate safety and/or trade risks without demonstrable benefits. One piece of information provided on the approved label for a TNP – the lowest dosage that has the intended effect – necessarily involves reviewing the efficacy of the product.

The options for requirements for efficacy (above) would make no difference to managing risks, as MPI's risk assessment examines different issues and uses different information from what would be needed for it to consider efficacy.

All of the options would, to a greater or lesser extent, provide more information and confidence to users and policy agencies.

However, all of the options would also generate extra costs to suppliers, with more information to be generated and provided to MPI, and additional MPI assessment time. As is the case for risk assessment, it is not possible to estimate what these costs would be; but as a generalisation, the more specific the efficacy requirements are, the greater the required information and costs would likely be.

There were mixed views among submitters on this question, with a majority indicating that there should not be a minimum level of efficacy required for inhibitor products.

Among both those that supported and opposed a minimum level, there was agreement that products should be required to validate claimed benefits with scientific evidence. This is consistent with current MPI assessment practices.

In line with current practice, MPI will need to develop and publish guidelines about efficacy so that suppliers are clear about the data they need to generate and supply as part of a TNP application. Given the level of uncertainty identified above, we cannot make any robust 'in principle' judgments about the balance between better information and extra costs for the different options. Therefore, we conclude that it will be necessary to develop specific options for definitions of efficacy (ie specific wording), and test them with industry.

Section 5: Conclusions

5.1 What option, or combination of options is likely to best address the problem, meet the policy objectives and deliver the highest net benefits?

On the basis of the above analysis, we conclude that the proposal to bring inhibitors within the scope of the ACVM Act, by classifying them as 'agricultural compounds', best meets the assessment criteria and is the preferred option.

While the available evidence specific to inhibitors is limited, we are confident that the proposed solution is consistent with MPI's general approach to regulation of food safety, animal and plant health and export trade.

The proposal is also consistent with the views of almost all submitters on the consultation.

With regard to provisions for transition, we conclude that a two-year timeframe would be sufficient to enable existing inhibitors to be registered; and a longer transition period for these products will only result in higher safety and/or trade risks.

As noted in the analysis, there are two commencement dates for this period; for:

- existing requirements not related to efficacy – two years from commencement of the relevant regulations
- efficacy requirements - two years from MPI issuing guidelines about efficacy.

With regard to efficacy, a minimum level of some sort is needed to justify registration and establish minimum effective dosages. However, we do not have a preferred basis for establishing the minimum level in principle from this analysis. MPI will need to develop specific options for efficacy; and test the balance between better information and extra costs for each option with industry.

5.2 Summary table of costs and benefits of the preferred approach			
Affected parties *(identify)*	**Comment**: nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks	**Impact** $m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts	**Evidence certainty** (High, medium or low)
Additional costs of proposed approach compared to taking no action			
Regulated parties (including suppliers and users)	Significant up-front costs of generating and providing evidence of inhibitor impacts, including regulator's assessment costs (below) Minor ongoing regulatory costs (eg maintaining a registry of approved products) These costs will initially be met by suppliers; however, as supply is on a commercial basis, costs will to a greater or lesser extent be passed on to users.	Unknown – upfront costs could be up to of $10,000 to $500,000 per product. Ongoing costs are trivial – under $1,000 per annum.	Low Number of products seeking regulatory approval and costs per product unknown
Regulator (MPI)	None, as costs are fully cost recovered.	None	High
Wider government			
Other parties			
Total Monetised Cost			
Non-monetised costs		High	Low
Expected benefits of proposed approach compared to taking no action			
Regulated parties	Greater certainty about safe and appropriate use of inhibitors	Medium	Low
	Significant reduction of risks of trade disruption, with resulting loss of export sales	High	Low
Regulator (MPI)	Significant reduction of risks of trade disruption and resources required to resolve these.	Medium	Low
Wider government	Better environmental outcomes through reduced emissions and less nitrogen leaching into waterways	High	Medium
Other parties			
Total Monetised Benefit			
Non-monetised benefits		High	Low

Section 6: Implementation and operation

6.1 How will the new arrangements work in practice?

It is proposed to bring inhibitors within the scope of the ACVM Act by declaring them to be 'agricultural compounds' through an Order-in-Council.[6]

After this is done, suppliers of products claiming to be an inhibitor would need to register them as 'Trade Name Products' (TNPs) with MPI, which requires an assessment of scientific data. MPI will need to provide specific advice and guidance on what data is required for the registration of inhibitors.

There are no other agencies directly involved in this registration process, but the usual approval requirements under HSNO will continue to apply.

A transition phase will be necessary for those products currently on the market, and a proposed transition periods of two years will provide time for companies to gather the required information.

6.2 What are the implementation risks?

There were two implementation issues identified through consultation:

- MPI's capability to assess scientific evidence about the safety of inhibitor products
- compliance costs to suppliers (for both generating evidence and for MPI to assess it); if these costs are too high, they could become a barrier to adoption of inhibitors

We cannot be certain about the level of MPI resources required to assess scientific evidence about inhibitors, given the uncertainty about the number of potential applications and the amount of evidence needed for each. However, we expect the number to be low relative to the total number of applications for new and amended registrations (2,600 annually); and if necessary, MPI can commission external scientific expertise (at the applicants' expense) to provide the required level of resource.

Compliance costs are inevitably a risk of this system. MPI attempts to avoid unnecessary compliance costs through:

- relying on applicants submitting data that they have already provided to other governments in support of applications for equivalent registrations elsewhere – recognising that virtually all ACVM products used in New Zealand are developed and introduced in other countries first, so NZ-specific information should be required only with regard to safe and effective use in local conditions
- providing industry with comprehensive guidance material about how inhibitors will be assessed; assuming that existing guidance with regard to risks such as public health, animal or plant health, residue management and trade in primary produce will be used, and additional material relating to efficacy will be thoroughly tested with industry before being incorporated in guidance material.

While the Act provides for low-risk classes of ACVM products to be exempt from TNP registration, MPI is expecting that all inhibitor products will need to go through the registration process. There is a possibility that some inhibitors may be low risk – ie under normal processes could be considered for exemption from registration. Should it be

6 An alternative approach is to amend the definition of 'agricultural compound' in the Act to include inhibitors. This would significantly increase time and costs without offering any advantages over an Order-in-Council.

determined certain inhibitors could be more appropriately managed by such an exemption, then the ACVM Regulations can be amended to include them. Alternatively, if they still require registration, reduced data requirements could established for this.

Section 7: Monitoring, evaluation and review

7.1 How will the impact of the new arrangements be monitored?

MPI will monitor implementation of the regulatory changes to ensure they remain up to date and fit for purpose as part of its ongoing programmes and processes. This includes a number of ongoing methods of assessing the impact of the regulatory system, including:

- food monitoring programmes to ensure food produced in New Zealand is safe and suitable, by establishing safe levels for residues, contaminants and other hazards
- stakeholder engagement forums including the Agricultural Compounds and Veterinary Medicines Advisory Council (ACVMAC)[7] (which meets quarterly) and feedback from industry
- information gained from requests at the border to determine if an imported product is exempt or not
- site audits to check compliance and evidence of good manufacturing practice.

7.2 When and how will the new arrangements be reviewed?

There is no plan to conduct a formal review of these amendments within a particular timeframe. However, as has always been the case, stakeholders will raise issues about the application of the ACVM Regulations, and feedback from the sector will provide information about whether and when to review the ACVM Regulations again.

The regulation of classes of products under ACVM are regularly assessed, and in some cases classes of low-risk products can be exempted from some aspects of regulation.

7 ACVMAC consists of industry groups representing sectors involved in the sale or use of agricultural compounds, and a consumer representative. Its purpose is to provide balanced advice to MPI on matters relating to the regulatory control of agricultural compounds and veterinary medicines.