Agricultural and Horticultural Products Regulatory Review

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2. Dr Joseph Morrall, Director, Agricultural and Veterinary Chemicals Policy, Australian Department of Agriculture, Fisheries and Forestry

Executive Summary

Background on agricultural and horticultural products

Farmers and growers use a range of agricultural and horticultural products in their businesses, including feeds, fertilisers, veterinary medicines, pesticides, and environmental inhibitors. Access to these products is important to maintain competitiveness, facilitate innovation, increase productivity, boost exports, support biosecurity and improve outcomes for animal, plant and human health, and the environment. The agricultural and horticultural products industry is a key input for New Zealand's major exporting sectors. The relevant downstream sectors generate over $43 billion in export revenue and contribute close to 10 percent of national gross domestic product. New Zealand faces a competitive disadvantage in terms of accessing products, given its relatively small size, reliance on minor crops in international terms, different farming practices and remoteness from main manufacturing bases.

While agricultural and horticultural products have many benefits, they also pose risks to human, animal and plant health, trade, and the environment. There is a role for government in helping to manage these risks.

In New Zealand, access to these products is managed by two regulatory systems under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and the Hazardous Substances and New Organisms (HSNO) Act 1996. They are administered by the Ministry for Primary Industries (MPI) and the Ministry for the Environment (MfE) and regulated by New Zealand Food Safety (NZFS), an MPI business unit, and the Environmental Protection Authority (EPA), a Crown entity.

The ACVM-HSNO approval path is part of a global risk management ecosystem that includes both regulatory and non-regulatory measures. This ecosystem continues to evolve and is facing new challenges, including changing expectations from customers of New Zealand's exported produce and the impact of technology and science.

Purpose and scope

The Agricultural and Horticultural Products Regulatory Review (the Review) seeks ways to improve efficiency and access to these products to contribute to economic growth while maintaining the effectiveness of the regulatory systems and ensuring that product risks are appropriately managed.

Key findings

- **The regulatory systems are effective in managing risks** to human, animal and plant health, trade, agricultural security (biosecurity) and the environment. However, the approval path does not always enable efficient and timely access to agricultural and horticultural products.
- **The most concerning issue is that the current approval path can be time consuming and uncertain.** It is not easy to estimate how long an application stays in the EPA queue and the total length of the approval path across the two systems. Industry and stakeholders believe that the length and uncertainty of the approval path have caused significant impacts on industry, end-users and may exacerbate New Zealand's competitive disadvantage.
- **Interface issues across the two approval systems have resulted in additional regulatory burden on industry and the primary sector.** The approval path was intentionally split across two systems in the 1990s to ensure effective management of environmental and safety risks as well as risks to trade, animal welfare, agricultural biosecurity, food residues and other matters. While choosing this design, the law makers anticipated complexity and inefficiency which have been realised in practice.
- **There are efficiency concerns relevant to the approval path**. These include using international regulators' information to the fullest extent and utilising 'light-touch' pathways, where appropriate, to ensure the proportionality of regulation for some products (and uses of products) and some applications.
- **There are concerns around regulators' resources, tools, and engagement.** The EPA is relatively under-resourced and has lower cost recovery levels than comparable regulators. It is important that cost recovery is transparent, leading to improvements in assessments, and industry funding is efficiently used by both regulators. The EPA's risk assessment models are no longer fit for purpose, and the ACVM data assessor framework is lacking sufficient oversight to effectively and efficiently facilitate regulators' assessments. Working with limited resources, regulatory agencies have put significant efforts towards engaging and communicating with regulated parties but there is still room for improvements, both at operational and strategic levels.
- **There is currently no strategic approach for an approval path split across two regulatory systems**, leading to issues relevant to strategic outlook, horizon scanning, prioritisation and slow regulatory responses to evolving regulatory environment. We consider the systems have not achieved the balance of risk management, enabling commercial

and innovative opportunities for growth, and minimising the unintentional consequences of regulation. During the Review, we have observed the *break-down of trust and confidence* between regulators and some regulated parties, which suggests changes are needed.

- **There is a need to ensure regulation of agricultural and horticultural products does not add unnecessary burden on the primary industries, given New Zealand's market characteristics**, especially its competitive disadvantage. It is also important that regulators and policy agencies are abreast of global trends and consider the value of non-regulatory risk management initiatives, which could contribute to effective management of product risks. If New Zealand's systems do not continue to be pragmatic and proportional, they may fail to support the primary industry sector.

Recommendations

The efficiency of the approval path must be improved to enable more timely access to agricultural and horticultural products (and uses of products) while still maintaining effective management of products risks. To achieve this, we have made 16 recommendations:

Issue: Lack of strategic direction

1. Establish a Sector Leaders Forum that brings together policy and regulatory agencies and stakeholders at a senior level to improve transparency and facilitate strategic discussions for the whole approval path.
2. Responsible Ministers use their available levers to prioritise prompt implementation of the Review's recommendations and consider issues raised by the Sector Leaders Forum on an ongoing basis.

Issue: Long application queues and assessment time

3. Minister for the Environment and Minister for Food Safety request specific and ambitious targets to reduce HSNO and ACVM applications queues and accelerate assessment process.

Issue: Complexity of the approval path across the two regulatory systems

4. Make the two regulatory systems easier to navigate by better coordination between the two regulators, for example offering combined guidance, sharing industry knowledge and technical expertise, and supporting alignment of workable controls.

Issue: Disproportionate and inefficient regulation

5. Increase the use of HSNO rapid pathways and group standards, ACVM registration exemptions and self-assessments for appropriate product and application types.
6. Reduce ACVM efficacy requirements for inhibitors to the minimum required to manage risks.

7. The EPA and NZFS further use international regulators' assessments to save time and resources.
8. The EPA and NZFS prioritise engagement at the international level to support harmonisation of requirements.
9. NZFS and the EPA explore a strategic pathway for priority products to mitigate the impacts of waiting time in the current queues.

Issue: Concerns about regulators' resources, tools, and engagement

10. Update the EPA's outdated risk assessment models and considering how to keep them up to date for the future.
11. Review HSNO cost recovery provisions.
12. Strengthen the framework overseeing ACVM independent data assessors.
13. The EPA and NZFS improve their performance reporting, and the Ministry for the Environment and Ministry for Primary Industries review statutory timeframes.
14. The EPA and NZFS prioritise the provision of up-to-date guidance, pre-application support, and transparency on application processing.
15. Extend existing NZFS and EPA stakeholder engagement forums to operate across both regulatory systems for agricultural and horticultural products.
16. Review HSNO emergency provisions to better enable products to be approved for biosecurity responses.

As a package, the Review's recommendations are expected to improve the proportionality, efficiency, transparency and certainty of the approval path.

While the complexity of an approval path across two regulatory systems will remain to some extent and New Zealand's competitive disadvantage will continue to be an on-going challenge, the Review considers the recommendations will support timely access to products and uses of products while continuing to effectively manage product risks.

To support Cabinet decisions on the recommendations and the implementation of Cabinet-agreed recommendations, Ministers will receive advice from agencies on work programmes to implement the Review's recommendations.

The Ministry for Regulation will provide relevant advice to Ministers and agencies at appropriate points during implementation.

Chapter 1: Introduction

This chapter outlines the reason for, and the purpose and scope of, the Agricultural and Horticultural Products Regulatory Review (the Review). It also summarises the Review's process.

1.1. The need for the Review

One of the Ministry for Regulation's functions is to carry out regulatory reviews. These reviews focus on regulatory issues that are of national significance. They identify opportunities to improve existing regulation, and where the Ministry for Regulation can partner with regulators to better design and operate their regulatory systems. The Agricultural and Horticultural Products Regulatory Review is the second regulatory review by the Ministry for Regulation.

Agriculture, which includes horticulture, is the largest sector of New Zealand's tradeable economy, with $54.6 billion in export revenue expected in 2024 and represents about 80.9 per cent of all merchandise exports (Ministry for Primary Industries, 2024c). In addition to direct contribution to the economy the agriculture sector is a significant employer, not only across rural and regional New Zealand, but also in major urban areas.

Farmers and growers use a range of products in their businesses, including feeds, fertilisers, veterinary medicines, pesticides, and environmental inhibitors. Access to these products and their various uses[1] is important to maintain competitiveness, facilitate innovation, increase productivity, boost exports, support biosecurity and improve outcomes for animal, plant and human health, and the environment.

While contributing significant benefits to primary industries, these products can also pose risks to human and animal health, the environment, and wider trade interests. Governments internationally have adopted regulatory approaches to manage access to these products. In New Zealand, access to these products is managed by two regulatory systems under the Agricultural Compounds and Veterinary Medicines (ACVM) Act and the Hazardous Substances and New Organisms (HSNO) Act. They are administered by the Ministry for Primary Industries (MPI) and the Ministry for the Environment (MfE) and regulated by New Zealand Food Safety (NZFS) – an MPI business unit, and the Environmental Protection Authority (EPA) – a Crown entity.

Farmers and growers have expressed concerns about difficult access to useful products for their business. While access to some older, sometimes environmentally unfriendly, products is removed by regulatory decisions (reassessment decisions), they have not been able to access newer, more innovative and safer products and various uses of products that are available overseas. Farmers and growers feel approval and registration of

[1] In this report, when we discuss access to new products, we mean access to new products and new uses of existing products.

new products are not being prioritised and facilitated. They believe this results in limited access to the tools they need to sustainably run their business and impacts on their export potential. There have also been concerns about the delayed access to products that can support improved biosecurity, animal welfare, productivity, and environmental outcomes.

1.2. Purpose and scope of the Review

1.2.1. Purpose

The Review seeks to assess whether the current approval path is maintaining an appropriate balance between enabling farmers' and growers' access to agricultural and horticultural products and managing risks associated with those products.

1.2.2. Scope

The subject of this Review is the assessment and approval processes, including reassessments, of products regulated under the ACVM and HSNO regulatory systems, including the interface between the two systems. The Review does not examine other functions of the regulatory systems, such as compliance, monitoring and enforcement, but may make some linkages to these functions where they may have impacts on the approval path. The Terms of Reference provide details on the purpose and scope of the Review.

1.3. How we undertook the Review

1.3.1. The engagement process

The Ministry for Regulation received more than 80 written submissions and has met with over 50 representative groups and companies including but not limited to primary producers, major exporters, product producers, environmental interests, public health, and research and development.

We held workshops with a Sector Reference Group to confirm and verify issues and underlying causes of the issues raised about the approval path as well as understand potential impacts of various options. During the Review, the team worked closely with core agencies, including MPI, NZFS, MfE, and the EPA. The team also received advice from a Senior Officials Advisory Group, consisting of senior officials from relevant regulatory and policy agencies throughout the Review. We engaged with other government agencies and organisations that have a specific interest in the management of these products.

The team engaged with Australia's Department of Agriculture, Fisheries and Forestry to learn about their regulatory experience and lessons.

We worked with the EPA to reach interested Māori parties and seek their feedback. Māori have an interest in and rights relevant to the management of agricultural and horticultural products. As our recommendations require further work by agencies and to reduce engagement fatigue, it is best that the required engagement and consultation with iwi/Māori take place when agencies develop final proposals for changes.

1.3.2. Our analysis

Our analysis was informed by a mixture of desktop research, engagement, and qualitative and quantitative methods. This includes an economic analysis to confirm the market failures that warrant Government intervention and a quantitative economic assessment of different scenarios of changes in terms of time or access to products. We predominantly undertook qualitative analysis of submissions and engagement feedback.

We endeavoured to verify the issues raised by agencies, industry, other stakeholders and the public, and identify the underlying causes of those issues. Our ability to verify the issues has in some cases, been constrained by factors such as the need to maintain the confidentiality of submitters' identities, the lack of detailed information in submissions, and the inherent complexity of externally assessing some issues, especially those that relate to practice or culture.

In some instances, we have been able to collect sufficient direct evidence to form a position. In other instances, we used proxies or our own analysis to understand the issues raised. In some places, we were unable to verify issues and have noted the opposing views we heard. We learned lessons from international and domestic regulatory systems, such as from Australia's chemical regulatory systems and Medsafe New Zealand. We note the differences in regulatory context and regulatory policies; therefore, our focus was on their approaches in managing risks associated with agricultural and horticultural products. Specific lessons learned will be noted in the following chapters reporting our analysis and findings.

1.4. Summary

Together, agriculture and horticulture are the largest sector of New Zealand's tradeable economy. Given the size of the sector, even small improvements in productivity or the value of exports, or reductions in input costs, could have an impact on the economy at a national level.

Farmers and growers need to stay competitive to increase exports and maintain prosperous rural communities.

The Review aims to identify opportunities to support farmers and growers to have improved access to new agricultural and horticultural products in a timely manner, while maintaining the effective management of products' impacts on human, animal and plant health, trade reputation, and the environment.

Chapter 2: Agricultural and horticultural products market and regulatory context

This chapter sets the scene for our analysis and findings. It provides background information on agricultural and horticultural products in scope of the Review and describes the markets for these products and key trends.

This chapter also summarises the key risks of the products, identifies market failures that require regulatory intervention, and sets out the regulatory frameworks managing the risks specified in relevant legislation. It outlines some non-regulatory initiatives that contribute to risk management of agricultural and horticultural products.

2.1. Markets for agricultural and horticultural products

2.1.1. Agricultural and horticultural products

Farmers and growers use a range of agricultural and horticultural products to protect and manage their animals and plants. The key types of products, their uses and benefits are shown in Table 1.

Table 1: Agricultural and horticultural products and their benefits

Products	Benefits
Agricultural and horticultural chemicals: • herbicides • fungicides • insecticides • plant growth regulators	Reduce weeds, prevent or manage fungal diseases, control insects and other pests, regulate growth and improve productivity.
Veterinary medicines: • analgesics/anti inflammatory • antibiotics • parasiticides • nutrient/electrolytes • vaccines	Diagnose, prevent or treat conditions in animals. Increase animal production, protect and maintain welfare for production, companion, sports and service animals.
Vertebrate toxic agents	Manage or eradicate vertebrate pests.
Pet food and animal feed	Provide food for companion animals and productive animals, fulfil nutritional requirements.
Environmental inhibitors	Provide benefits and/or mitigations related to climate change (primarily methane inhibitors and nitrogen/nitrification inhibitors).
Fertilisers	Improve productivity of pastures and plants.

The agricultural and horticultural products industry includes manufacturers (who are mostly multinational companies headquartered overseas), importers, distributors, and service providers (for example, spray contractors or firms that advise on usage). Though there are no official revenue and employment numbers, the industry is relatively small within the New Zealand economy.[2] It is also small in international terms. As an example, total pesticides (broadly herbicides, fungicides and insecticides combined) used or distributed in New Zealand account for around 0.1 per cent of total tonnes used worldwide (Table 2).[3]

Table 2: Pesticide (agricultural) use in New Zealand vs other countries (tonnes, year 2022)[4]

	Herbicides	Fungicides	Insecticides	Pesticides total
New Zealand	2,914	1,315	303	5,285
Australia	44,581	3,672	11,060	59,634
Canada	75,280	12,474	4,816	97,692
EU (27)	112,374	137,876	53,979	327,647
United States	405,497	15,075	7,798	467,677
Worldwide	**1,942,558**	**794,240**	**774,797**	**3,697,553**

Source: FAOSTAT: https://www.fao.org/faostat/en/#data, combination of estimated values and imputed values.

Table 3: New Zealand export revenue (forecast to year ended June 2024) for sectors using agricultural and horticultural products

Product/ Sector	Export revenue (NZ$ m)	Total (%)
Dairy	24,160	56
Meat	8,866	20
Horticulture	5,030	12
Animal products	2,523	6
Wine	2,090	5
Honey	420	1
Arable	310	1
Total	**43,399**	**100**

Source: MPI: Source: Situation and Outlook for Primary Industries, June 2024

While not significant in a global sense, the local agricultural and horticultural products industry is a key input for New Zealand's major exporting sectors. As shown in Table 3, the relevant downstream sectors generate over $43 billion in export revenue and contribute close to 10 percent of national gross domestic product (GDP).

Industry-commissioned reports estimate that without animal and plant protection

[2] The animal protection products segment of the agricultural and horticultural products industry had turnover of $450 million and 1,100 employees (KPMG, 2021).

[3] There is currently no reliable New Zealand data for the quantities of pesticides used in New Zealand. From 2026 new requirements mean reporting on the quantities of some hazardous substances (including most agrichemicals) being imported into and manufactured in New Zealand will provide more reliable information. *https://www.epa.govt.nz/public-consultations/decided/proposal-importers-and-manufacturers-notice/*.

[4] New Zealand stopped providing data from 2009, so this data is representative of 2009.

products, New Zealand would lose close to half of this revenue (NZIER, 2019; KPMG, 2021).

2.1.2. Market structure

The market for agricultural and horticultural products has both a global and local dimension. Its features have implications for how it is regulated.

The manufacture of new active ingredients in agricultural and horticultural products is dominated by a small number of multinational companies. The average discovery and development cost of a new crop protection product of this kind was, between 2014 and 2019, estimated to be around USD 300 million (NZD 460 million, 2019) (Agbioinvestor, 2024). To recover an adequate return on their investment, these products need to be manufactured "at scale" and tend to focus first on staple crops[5] and production animals in major markets.

New Zealand also has a number of smaller, local companies involved in the manufacture of agricultural and horticultural products. This segment of the industry typically focusses on development of generic products or provides innovation through reformulation of an existing active ingredient.[6]

2.1.3. New Zealand market characteristics

In addition to being a relatively small market, there are several New Zealand-specific characteristics that are relevant for the Review. The major crops grown in New Zealand are minor on a global scale. Apples, our largest crop, represent just 0.6 per cent of global production (Table 4). There is less incentive to develop new products (or add more uses of products) for minor or speciality crops. Countries like Australia, the USA and Canada provide support programmes to develop products that may not otherwise be commercially available (Eather, et al., 2020, Office of Audit and Evaluation, 2018, Miller and Mann, 2022).

Another cost-related issue for New Zealand is its physical distance from manufacturing centres. Large companies operate global supply chains based on just-in-time inventory.[7] Smaller markets often bear the brunt of any delays or shocks to the supply chain, with priority given to higher-margin markets. Such uncertainties can also influence investment decisions. New Zealand's isolated location can add to the level of commercial risk, which then requires a higher return on capital compared to other markets multinational firms have access to.

[5] According to FAOSTAT the major crops are wheat, maize, rice and barley.
[6] Generic products are manufactured and sold by companies other than the original manufacturer, once the original product's patent or data protection expires. They contain the same active ingredient(s) at typically the same concentrations as "branded" products. Based on stakeholder engagement and advice from an independent consultant, the cost of developing a product with an existing active ingredient is estimated to be $2-4 million.
[7] A just-in-time system achieves efficiencies and reduces inventory by aligning inputs, production and distribution schedules.

Table 4: Production quantity of four crops, New Zealand vs other countries (tonnes, year 2022)

	Apples	Kiwifruit	Maize (corn)	Wheat
New Zealand	575,553	603,523	188,249	402,557
Australia	300,518	2,418	430,000	36,237,477
Canada	380,571	28	14,538,878	34,334,787
EU (27)	12,559,280	971,110	52,970,670	134,326,040
United States	4,429,330	33,110	348,750,930	44,902,320
Worldwide	**95,835,965**	**4,539,471**	**1,163,497,383**	**808,441,568**

Source: FAOSTAT: https://www.fao.org/faostat/en/#data, combination of official figures and imputed values.

New Zealand farming practices differ from those of many larger agricultural countries. We typically use a pasture-based system that allows animals to graze in fields, whereas many overseas countries use feedlots. This affects how products are used and risks are managed.

In some cases, agricultural and horticultural products manufactured for global markets may not be appropriate for use in New Zealand, even if already approved by regulators in other jurisdictions. How the product is used by local farmers and growers has the potential to impact efficacy and residues, while different soil, climate, and physical environment can impact the way a chemical disperses in the environment.

Maximum Residue Levels (MRLs)[8] are also an important consideration for New Zealand. The use of agricultural and horticultural products can leave residues in resulting food or elsewhere in the food chain. The use of approved products in New Zealand can be restricted by MRL requirements in importing countries.

Many of these factors combine to put New Zealand at a competitive disadvantage when it comes to accessing and using agricultural and horticultural products. This can mean that New Zealand farmers and growers miss out on the same suite of innovative tools as their overseas competitors.[9]

[8] In this report, when we talk about MRLs, we include import tolerances, which are MRLs set specifically for imported products.

[9] An exception is exports to Australia, given the Trans-Tasman Mutual Recognition Agreement applies to food produced in accordance with each country's MRLs.

2.1.4. Key Trends

There are several global trends influencing the market for agricultural and horticultural products. The two key ones are changing consumer preferences in export markets and expectations and shifts occurring within the industry, especially at a global level.

Food standards are being increasingly driven by consumers exerting their values regarding sustainability and climate change. These expectations, which are particularly evident in Europe, can sometimes exceed regulatory levels.

Market and shareholder pressures are resulting in global companies and food importers (for example, supermarket chains) putting in place policies and commercial agreements designed to influence how food is produced further up the supply chain.[10]

Some policy makers are responding to consumer-driven expectations. To meet contemporary food safety standards, the EU, for example, is revoking product registration of numerous active ingredients used in the protection of plants and animals from pests and diseases. High risk products are being replaced by "softer" products and biological based products.[11] The EU is also adopting "stretch targets" for food safety.[12]

These changes, along with weak farm profitability and growth in alternative crop protection technologies (for example, biologicals/bio-stimulants, genetically modified crops), are impacting the traditional industry (Phillips, 2019).

[10] The Environmental, Social and Governance risk framework adopted by major manufacturers is a general example. A more detailed example is Tesco adopting a comprehensive pesticide policy where compliance is monitored via audit and testing programmes.
[11] For example, EU Regulation 1107/2009 imposes certain hazard-based criteria for active substance approval in the EU. We note some newer chemistry that is lower in toxicity to humans caused significant problems for bees worldwide (neonicotinoids) and required global cooperation to improve assessment of products for toxicity to bees and pollinators.
[12] The Farm to Fork Strategy requires a 50% reduction in chemical pesticides.

2.2. Risks posed by agricultural and horticultural products

2.2.1. Products risks

Figure 1: Key risk categories[13]

While agricultural and horticultural products have many benefits, such as improving productivity in crops and animal production, they also pose risks to people, animals, the environment and New Zealand's trade. As shown in Figure 1, the Review considers there are three categories of risk relating to the regulation of products. Table 5 provides details on the nature and impact of these risks.

These risks can lead to market failure concerns that warrant government intervention. The two key market failures for agricultural and horticultural products are:

- information asymmetries – insufficient or incorrect information is provided by manufacturers to end-users about risks (discussed above), leading to harm and unintended consequences; and
- externalities – manufacturers and end-users do not bear all the consequences of causing harm.

Market failure definitions are provided in Appendix 1, while Chapter 4 includes discussion on the role of government.

[13] The categories are the Review's conceptualisation of the risks. This is not reflected in the ACVM Act or HSNO Act.

Table 5: Description of risks

	Risk or harm
Human health (usage)	Product causes safety concerns due to its uses by applicators/operators, workers, farmers, and veterinarians. It can also impact residents or bystanders, though consequence or mitigation needed may be low.
Human health (food safety)	Chemical residue levels detected in food higher than safe thresholds, leading to impacts on consumers, both domestic and international, via exports. This risk can occur because product manufacturers do not disclose, knowingly or unknowingly, the risks of the product, such as changes in the chemical formulation or ingredients. Can also occur if end users, knowingly or unknowingly, use product incorrectly (for example, apply more than is recommended).
Animal health	Detrimental effects can occur to the target animal or plant caused by either incorrect use of product, or the product causes harm through contamination or side-effects.
Plant health	
Environment	Product can negatively impact drinking water quality, groundwater quality, soil quality, aquatic species (invertebrates, fish), soil organisms, non-target invertebrates and pollinators, terrestrial vertebrates (birds, reptiles/amphibians), plants (targeted and non-targeted). Effects may be localised or widespread, transient or permanent.
Trade	The use of agricultural and horticultural products can result in an event relating to the direct risks (for example, the detection of residues in food that exceed allowable levels), which then leads to both immediate and longer-term loss of trade opportunities.
Animal Welfare	Product does not provide therapeutic benefit, as it claims to be able to do, and the animal suffers unnecessary pain or distress as a result.
Anti-microbial Resistance	Product contributes to any resistance problems. A product may be efficacious overseas but not in New Zealand. For example, some internal parasites in sheep have developed resistance to several anthelmintic veterinary medicines. There are also broader antimicrobial issues, and resistance issues between human and animal/plant health.[14]
Agricultural security (biosecurity)	Product causes resistance concerns because it is not effective in managing or killing pests or diseases, potentially causing significant economic, social, environmental and cultural impacts.

[14] Antimicrobial resistance – Health New Zealand | Te Whatu Ora

2.2.2. Trade issues

If the direct risks to human, animal and plant health, and the environment, are not managed effectively, then residues in export food commodities can lead to significant damage to our trade reputation and affect market access. Overseas markets, which may react to perceived risks, can refuse to accept imported food and fibre. This can lead to major economic impacts, including loss of GDP and employment. Appendix 1 shows examples that highlight how crucial it is that trade risk, both perceived and real, is managed effectively.

The New Zealand government provides assurances to importing countries about food safety and a range of other matters (such as animal welfare or organics certification). This enables the free flow of food and fibre exports into key markets. Without this government-to-government assurance system and related processes such as a Codex Alimentarius (Codex), exporters would face significant transaction costs, such as delays at the border for testing.

International trade negotiation and facilitation can be considered a "club" good (see Appendix 1). The regulatory system is a fundamental component of this arrangement, assisting the government to negotiate further trade agreements. While its approval process is designed to ensure the direct risks of the products are effectively managed, it does this in a way that best facilitates trade.

2.3. Management of risks associated with agricultural and horticultural products

There are various bodies, regulations and measures that contribute to managing the risks associated with agricultural and horticultural products. The risk management ecosystem includes regulatory management, international standards and agreements, regulatory requirements and commercial expectations in importing countries, and industry-based initiatives.

In New Zealand, the regulatory management of agricultural and horticultural products primarily involves two pieces of legislation, the ACVM Act and HSNO Act.

2.3.1. New Zealand regulatory systems

ACVM

The ACVM Act regulates the importation, manufacture, sale and use of agricultural and horticultural products to prevent and manage associated risks to *public health, trade in primary produce, animal welfare, and biosecurity*. The ACVM regulatory system manages access to products through authorisation either via registration or exemption from registration (under the ACVM Regulations or as "generally recognised as safe" (GRAS)). Exempted products must still meet the conditions in the ACVM (Exemptions and Prohibited Substances) Regulations 2011 to minimise risks.

To register a trade name product (TNP) under the ACVM regulatory system, an

applicant must provide NZFS with an application including risk analysis and supporting technical data. NZFS appraises the application to decide whether the product can be registered (with or without specific conditions) or refused. Registration of a TNP is reviewed every five years to ensure ongoing safety, efficacy and compliance.[15] Renewals are to consider whether the product is still fit for purpose and to ensure all information held on the label, or in product data sheets, is up to date.

Registration of a TNP can be amended, for example, by updating chemistry or manufacturing information, adding or removing claims or target crops or species. The ACVM Act provides that when significant new information emerges, a registered TNP may be subject to reassessment by NZFS.

HSNO

Agricultural and horticultural products containing a hazardous substance are managed under the HSNO Act. New hazardous substances must be assessed and approved with appropriate controls.[16] HSNO approval is required to prevent or manage the adverse effects of hazardous substances and new organisms *to protect the environment and the health and safety of people and communities*.

Agricultural and horticultural products account for a minority of hazardous substances that the EPA regulates. The others include a wide range of industrial and household chemicals and other substances such as explosives, fuels, fumigants, paints, or food additives.[17]

Group Standards provide approval to substances of a similar nature, type, or use with conditions that must be met including those in line with EPA Notices.[18]

Under the HSNO Act, approved substances can be reassessed when new information or other circumstances indicate the need for a review of the controls or the approval itself. HSNO reassessments can be initiated by the EPA's Chief Executive (CE), industry or by any person or organisation.

- CE-initiated reassessments, which may be initiated following an application for grounds from a member of the public, an organisation, or as a result of the EPA's reassessment prioritisation. These reassessments generally consider whether the controls are still suitable for a substance or group of related substances, or whether the approval(s) should be revoked.
- Applicant-initiated reassessment, which typically seek to change the conditions or use patterns for a

[15] ACVM Registration Renewal

[16] Some ACVM products are covered by HSNO group standards (such as veterinary medicines or fertilisers). For these substances, each product is not individually assessed before being introduced into New Zealand. However, the appropriateness of these substances to be covered by a group standard with a uniform set of conditions, was considered at the time the group standards were established.

[17] New Zealand gives approvals to hazardous substances which contain one or more components or ingredients (chemicals). Active ingredient means the ingredient or ingredients in a formulated product that is or are primarily responsible for the biological or other effects of that product.

[18] For example, notices on labelling and advertising, safety data sheet, packaging, disposal, restriction on supply, storage and use EPA notices for hazardous substances | EPA.

specific substance. This is similar to an ACVM variation.

Once an agricultural and horticultural product is registered, its importation, manufacture, sale and use are subject to monitoring, compliance, and enforcement.

These functions are not in the scope of this Review.3

Some notable differences between the ACVM and HSNO regulatory systems

Table 6 describes key differences between ACVM and HSNO approaches in managing agricultural and horticultural products.

Table 6: Key differences between ACVM and HSNO regulatory systems

Issue	Difference and issues
Products vs substances	The ACVM system registers TNP (trade name products), whereas the HSNO system approves hazardous substances. It is possible for multiple TNP to be registered under one substance approval, particularly historical approvals transferred into the HSNO Act. The HSNO Act allows "matching" to existing approvals if the substance and hazard classifications match.
Limited time registrations vs perpetual approvals	ACVM registrations are normally for a 5-year renewal period. HSNO approvals have effect in perpetuity.
Data requirements	The ACVM system requires data to verify efficacy, residues, animal and plant health, and the chemistry and manufacturing quality.[19] The HSNO system requires toxicology studies, ecotoxicology studies, environmental fate, chemistry information and substance composition.[20] These differences arise because of the different risks being managed.
Assessing benefits	Under the HSNO Act, the EPA conducts a stand-alone assessment of the risks to the environmental and human health (use of substance), as well as considering the possible benefits of the substance. Benefits information is typically qualitative and provided by the applicant. NZFS requires applicants to submit efficacy data as part of its risk assessment. NZFS requires such detailed information to help it better understand benefits and risks. The latter covers animal welfare, agricultural security, trade, and public health (management of residues in food).
Labelling	NZFS approves the label content related to the ACVM Act that must be applied to the product.[21] The EPA does not approve specific labels, but labels must comply with the HSNO labelling notice[22] plus specific controls relevant to the individual substance.

[19] Registration Information Requirements for Agricultural Chemicals
[20] Hazardous-Substances-Data-Requirements.docx
[21] ACVM Guideline: Labelling Agricultural Chemicals
[22] Consolidated Hazardous Substances (Labelling) Notice 2017 | EPA

The ACVM regulatory system has a critical interface with the HSNO regulatory system

Some agricultural and horticultural products require both HSNO approval and ACVM registration. For these products, the ACVM regulatory system has a critical interface with the HSNO system. The ACVM Act replaced the previous Fertilisers Act 1960, Stock Food Acts 1946, and Animal Remedies Act 1967, and the HSNO Act replaced the Pesticides Act 1979 (and other legislation not relevant to agricultural and horticultural products). These Acts were administered by the predecessors to MPI.

In replacing these pieces of legislation, one of the reasons for transferring management of risks to the Environmental Risk Management Authority (a predecessor to the EPA) was to ensure management of environmental and safety risks was given sufficient priority. Management of risks relevant to trade, primary produce, animal welfare, agricultural biosecurity, and food residues was retained at the Ministry of Agriculture and Forestry and New Zealand Food Safety Authority (predecessors to MPI) (House of Representatives, 1997a). It was acknowledged in the development of the legislation that some products would need to go through both pieces of legislation and that there may be efficiency concerns. Alignment and consistency between the two bills were considered by the select committee and discussed in the House during the legislative process (House of Representatives, 1997b).

If an agricultural and horticultural product contains a hazardous substance or a new organism[23] regulated under the HSNO Act, ACVM registration cannot be finalised without a relevant HSNO approval from the EPA. When a product used in connection with food production contains an active ingredient that is new to New Zealand, the EPA provides NZFS with the dietary exposure values (if calculated) so they can be used to support setting an MRL.[24]

While most ACVM applications for a new TNP containing hazardous substances require an HSNO approval, either in the form of individual approvals or through group standards, approximately 90% of ACVM applications are variations to existing registered TNPs, which do not have an interface with the HSNO regulatory system.

Figure 2 describes a simplified flow diagram between the HSNO approval and ACVM registration process.[25] We note that in response to the Review's request for an interface diagram, NZFS and the EPA provided diagrams of the separate HSNO and ACVM processes and indicated the points of intersection (see Appendix 2). The Ministry for Regulation developed this diagram based on those diagrams and a range of assumptions noted in Appendix 2. We own any errors in the flow diagram as this is our understanding of the processes.

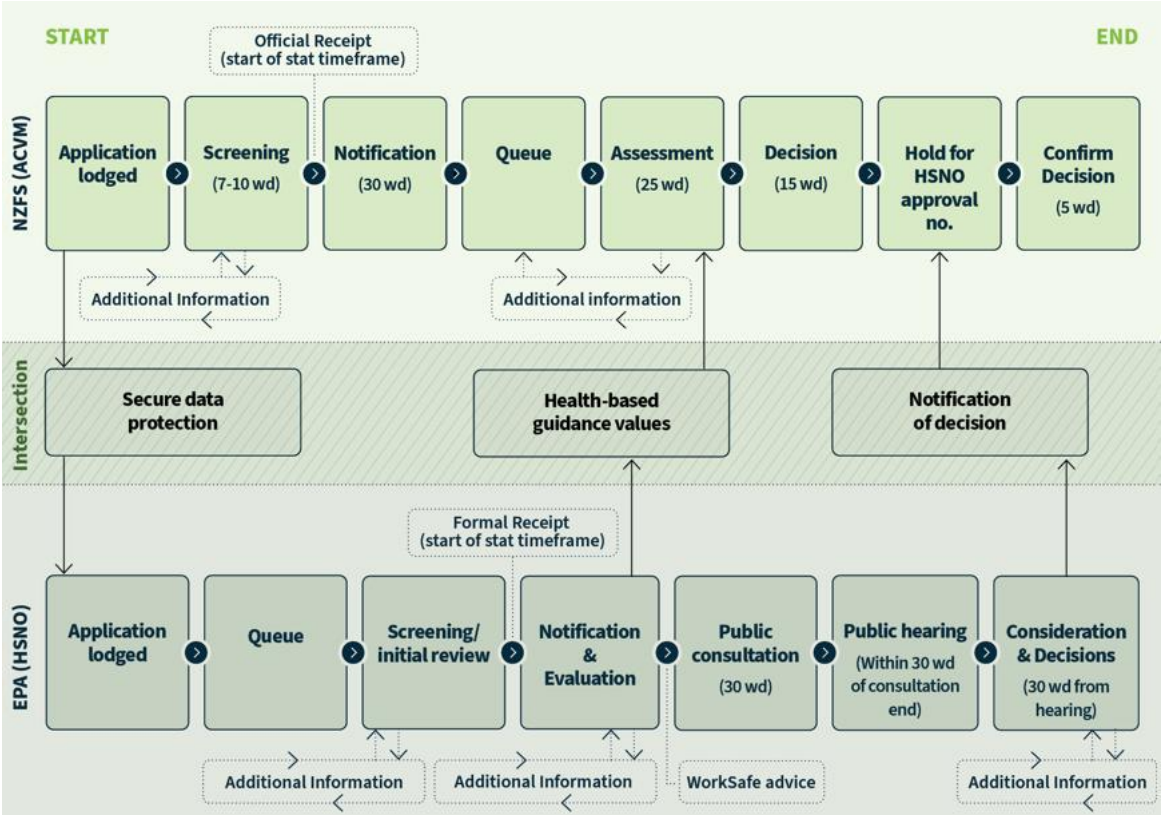
[23] Hazardous substances are chemicals or a mixture of chemicals that has one or more of the following properties: explosive, flammable, oxidising, toxic, corrosive, and ecotoxic. New organisms are defined in the HSNO Act and are not in scope for the Review.

[24] If a hazardous substance is covered under a group standard, this is a self-assignment process by the manufacturer/importer and the EPA does not undertake an individual assessment or provide NZFS with a health-based guidance value.

[25] The Review team has generated this figure for the purpose of the Review as no overview of the approval path was otherwise available.

This should not be relied on as guidance for any applicants.

Figure 2: Flow diagram for products requiring both an HSNO approval and ACVM registration



The ACVM and HSNO systems also have interfaces and relationships with other legislative systems

Agricultural and horticultural products with HSNO human health hazard classifications are automatically captured under the Health and Safety at Work Act 2015 (HSWA), the functions of which are undertaken by WorkSafe New Zealand. These are designed to protect workers. For some HSNO applications, typically those with a new active ingredient never approved in New Zealand before, the EPA will seek advice from WorkSafe New Zealand as part of the application process as per the requirements of the HSNO Act.

In addition to the HSNO Act, the ACVM Act has a relationship with other acts such as the Animal Products Act 1999, the Food Act 2014, the Wine Act 2003, the Animal Welfare Act 1999, the Biosecurity Act 1993, and the Medicines Act 1981. The ACVM Act statutory outcomes align with the outcomes stated in these related acts. It also has some relationships with the Veterinarians Act 2005 and the role of the Veterinary Council of New Zealand.

Costs and benefits of agricultural and horticultural products and regulation

In principle, the core purpose of the ACVM-HSNO approval path is to assess and manage the potential harm caused by agricultural and horticultural products. Risk reduction is the primary benefit of the regulations and is achieved by imposing restrictions on the availability and use of

the products. This creates a cost to regulated parties. As a matter of good regulatory practice, regulators should minimise these costs for an acceptable level of risk to society, recognising that it may be difficult to interpret different levels of risk. Least cost management includes enabling timely access to products and uses of products while maintaining the effectiveness of risk management.

While it is necessary for a regulator to understand the benefits associated with agricultural and horticultural products (for example, the benefits of controlling a pest), this is done for the purpose of making an informed trade-off between the management of risk (the benefit of regulation) and these foregone benefits (the primary cost of regulation) (see detail in Appendix 1).

2.3.2. Non-regulatory risk management

In addition to domestic regulation, international trade agreements and conventions, some of which are enforceable, local industry and overseas buyers of New Zealand commodities also have a role in managing risks associated with agricultural and horticultural products. For example, horticultural goods exported into the EU, from non-EU countries, are expected to meet EU regulatory standards and consumer expectations.

Codex and other international commitments

Codex Alimentarius (Codex) are international food standards and are based on the advice and opinions of the independent scientific expert committees of the Food and Agriculture Organization and the World Health Organization. Food standards are adopted by the Codex Alimentarius Commission, an intergovernmental body made up of 188 countries and one member organisation. While these do not usually have direct legal effects (unless incorporated by a country through their laws), they establish an internationally recognised and evidence-based benchmark (recognised by the World Trade Organization).

The management of agricultural and horticultural products also needs to align with relevant international commitments.[26]

Industry involvement in risk management

As discussed earlier, food safety, along with sustainability and climate change impact, is being increasingly influenced by consumer preferences in premium markets. Market forces interpret these often-subjective expectations. While many suppliers[27] are putting in place commercial arrangements that drive the behaviour of farmers and growers in New Zealand, evidence-based regulation remains the foundation of the food safety system.

[26] For example, the Paris Climate Change Agreement, Stockholm, Rotterdam and Basel conventions, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement), the Technical Barriers to Trade (TBT) Agreement, Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement, Organisation for Economic Co-operation and Development (OECD) Mutual Acceptance of Data (MAD), the Globally Harmonized System of Classification and Labelling (GHS) 7, the International Cooperation on Harmonisation of Technical Requirements for veterinary product registration (VICH).

[27] Such as supermarket chains in the United Kingdom and Europe or restaurants in Japan.

Regulators need to be aware of the impact of global trends within the risk management ecosystem. New Zealand also has examples of where regulators devolve certain responsibilities to non-government bodies.[28] Appendix 1 has examples of industry initiatives and programmes that contribute to the management of risks associated with agricultural and horticultural products.

2.4. Summary

Farmers and growers use agricultural and horticultural products to protect and manage their animals and plants.

These products are critical to primary industries and the economy. New Zealand's market for these products is relatively small, has to provide for different usage patterns, is affected by distinctive climatic and environmental factors, and is distant from major manufacturing bases.

These characteristics place New Zealand at a disadvantage in terms of access to a diverse range of agricultural and horticultural products compared to its overseas competitors.

Government intervention is needed to address market failures of information asymmetries and externalities which cause risks to human health, animal and plant health, the environment and trade interests and provide official assurances for market access.

[28] Society for the Prevention of Cruelty to Animals enforcement role under the Animal Welfare Act 1999 or Veterinary Council functions under the Veterinarians Act 2005.

Chapter 3: Issues in the approval path of agricultural and horticultural products

In this chapter we draw on evidence gathered during our engagement process including:

a. stakeholder meetings and a wider consultation exercise;
b. input from regulatory agencies including in-depth workshops;
c. a desktop review of the most up-to-date reports; and
d. our analysis

to identify and verify issues and underlying causes of the issues associated with the approval path of agricultural and horticultural products. We will report the issues of the approval path along these lines of enquiry:

a. the speed and timing of the approval path;
b. interface issues between the ACVM-HSNO systems;
c. efficiency of the approval processes;
d. proportionate regulation;
e. regulators' resources, tools, and engagement; and
f. strategic approach for the approval path.

3.1. The current approval path is uncertain and time consuming

As explained in Chapter 2, some agricultural and horticultural products need to go through both HSNO and ACVM assessment processes to be introduced and used in New Zealand. If someone wants to introduce a product with a new active ingredient into New Zealand, they will need to apply to the EPA for an HSNO approval of the hazardous substance and to NZFS for an ACVM registration of a relevant TNP. The two processes can be undertaken in parallel or in a sequential order. The HSNO application will enter the EPA 'queue' until it is formally received and then goes through the EPA assessment process which is legislatively time-bound. The actual assessing timeframes can be very different from the statutory ones. Similarly, the ACVM application also needs to enter an NZFS 'queue' before being assessed in a process that is also legislatively time-bound and can be varied in length.

3.1.1. There is a lack of certainty regarding actual process timeframes

The industry's primary concerns were not knowing how long applicants will have to wait in the EPA queue, and when time waivers are issued, how long it will take for the assessment to be resumed following the applicant's provision of additional information and when a decision is made.

Being able to predict with some level of certainty when a decision will likely be provided is important to business operations – some submitters expressed that certainty was more important than speed.

There is some reporting on regulators' websites and through newsletters for each system. The EPA has published data on completed HSNO applications on their website since 2022, and has begun providing more granular reporting, including the number of applications in the queue, since June 2024. However, applicants need more specific estimates for their applications. It is also challenging to predict how long it takes for a product to get through the two systems. There is currently no single estimate for this. We will discuss and estimate the timeframes below.

3.1.2. The processes are time consuming

Statutory timeframes

The ACVM and HSNO legislation sets specific timeframes for registration and approval processes excluding the time waiting in the queues. It is up to 70 working days under the ACVM Act and 100 working days under the HSNO Act, depending on assessment pathways. We have heard from regulators and submitters that these timeframes are unrealistic.[29] We note the original intent of the ACVM timeframe was to ensure a reasonable timeframe for products that need to go through two regulatory systems (House of Representatives, 1997b).

[29] Statutory/targeted timeframes for 'complex' applications of new active ingredients and actual time from commencement: the EPA (NZ): 100 working days and 30.5 months, APVMA (Australia): 18 to 25 months and 29 months, UK: 36 months and 78% within deadline, Canada: 24 months and 82% within deadline, EU: 18 months (Loan, et al., 2023). The EPA advised the EU statutory timeframes are 30-44 months and actual time is ~48 months. ACVM statutory and actual timeframes for a TNP with new active ingredient: 70 working days and >12 months.

Figure 3: HSNO queue in the last four years

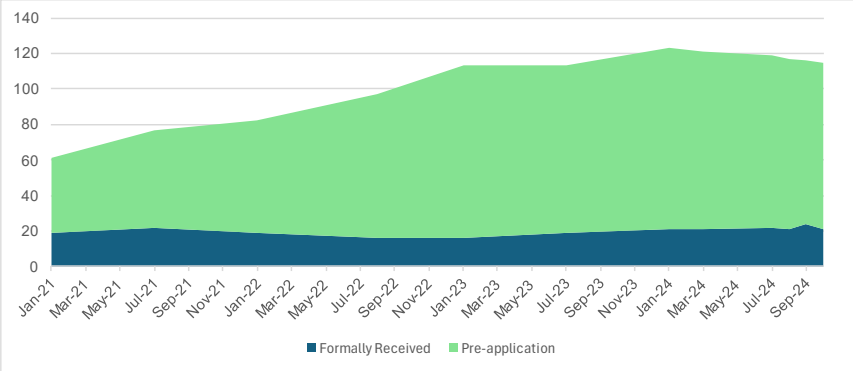
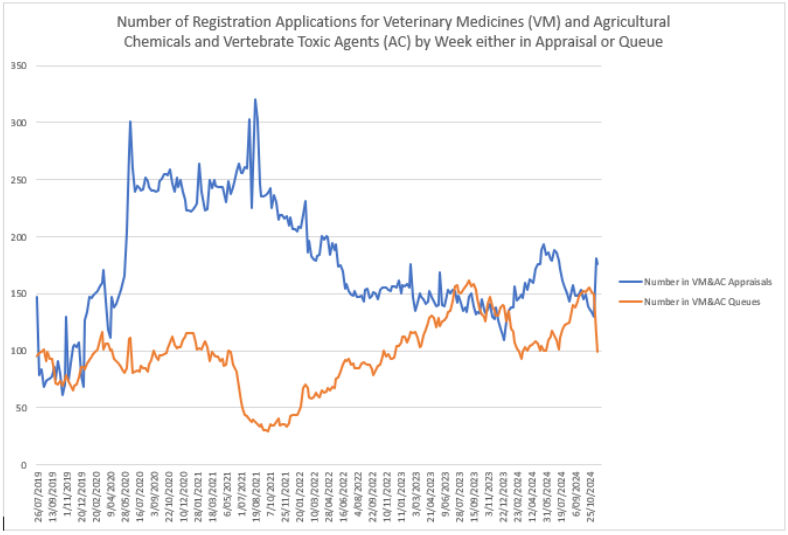


Figure 4: ACVM queue in the last five years



Actual processing timeframes

Most ACVM applications are for variations to existing products. These applications require fewer resources and less assessment time than new product applications. In contrast, the EPA queue only contains applications for new substances. Together with the time needed to pass through the queues, this means that the backlog at the EPA is more concerning because it delays the entry of new products into New Zealand. Figures 3 and 4 show the ACVM and HSNO queues over the last four/five years.

While all regulators have queues, when combined with New Zealand's competitive disadvantage discussed in Chapter 2, the EPA queue may further discourage the introduction of new products to New Zealand (Loan, et al., 2023, page 31).

ACVM process

A new TNP with at least one new active ingredient usually requires both HSNO approval and ACVM registration. The ACVM application can be filed before, during, or after the HSNO application, but cannot be registered until the EPA issues an HSNO approval.

The median time for registration of a TNP with new active ingredients from 2022 to 2024 is around 625 working days (32 months) (internal document). This includes time where the application is with the applicant for additional information and in the queue. The net median

processing time by NZFS is 209 working days (11 months).

The EPA process

The EPA's assessment times for substances containing new active ingredients are broadly similar to international regulators (Loan, et al., 2023, page 3). For the most complex HSNO applications for products containing active ingredients that have never been approved in New Zealand (Category C), the median application process has increased from 402 days (during 2013-2015, for 14 applications) to 1,048 days (during 2021-2023, for 8 applications) (Loan, et al., 2023, page 4). Of the nine HSNO applications provided by the submitter, four are still in processing time after 690 to 1,200 working days. The EPA's most recent quarterly report shows, as at September 2024, 17 applications still being processed after 611 to 1,752 days from lodgement, four of them are on hold for further information.

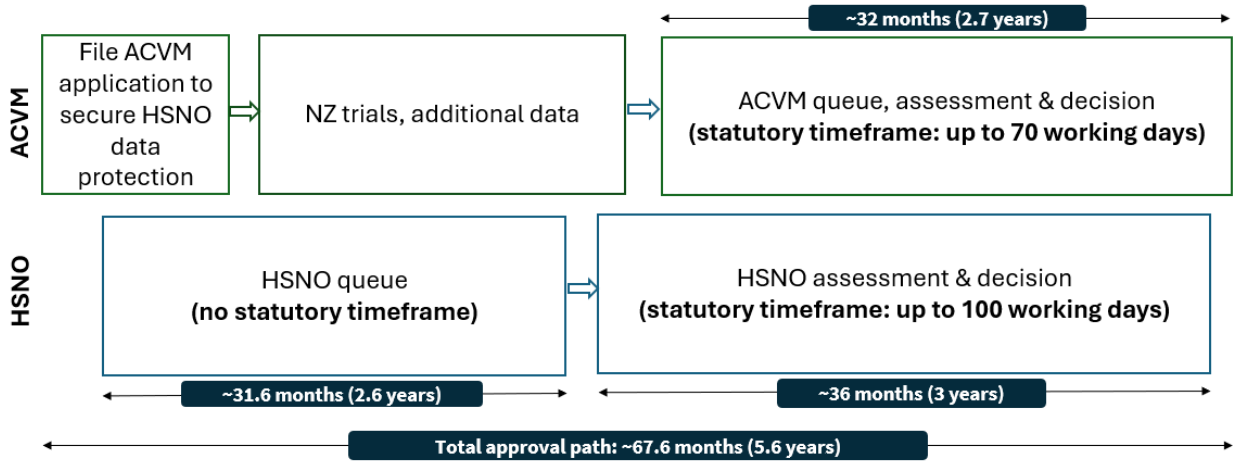
The EPA's website reports that 75% of Category C applications are processed from formal receipt to decision notified within 36 months. Adding the median queue time of 31.6 months would make the total end-to-end time for a Category C application approximately 67.6 months (5.6 years) if it is lodged today. This may include the time where the application is with the applicant for additional information. We note the completed application data reflects a period where the EPA had the lowest levels of specialised technical staff. As the EPA queue appears to be reducing following increased staffing levels and recent EPA effort to reduce the queue, we expect in practice this time could be shorter.

Estimated total HSNO approval and ACVM registration timeframes

As processing times by the two regulators are available in different forms and places, there is not a single source of information to estimate the actual approval time for a new product. We have calculated this using publicly available information and confidential data from regulators, based on a range of assumptions. The level of effort and time needed for the Review to capture the process and timeframes supports stakeholders' and submitters' claims regarding the complexity and length of the approval path.

Figure 5 shows a parallel filing approach that an applicant might follow to obtain HSNO approval and ACVM registration for a new TNP with a new active ingredient. We estimate the total processing time for this approach to be 67.6 months (5.6 years), subject to a range of assumptions (see Appendix 2). If an applicant takes a sequential filing approach, the total end-to-end time could be around 99.7 months (8.3 years). As noted, due to recent changes in the EPA queue, this can be different from the reality.

Figure 5: Review's estimated processing time of a new complex application for approval and registration in New Zealand based on a parallel filing approach



3.1.3. On-pause applications during the process

Once an application is formally accepted, the clock can be stopped and restarted if the regulators require further information. Both NZFS and the EPA (and international regulators) frequently receive applications with insufficient information. This contributes to prolonging the assessment process. Incomplete applications can be caused by a lack of due diligence by the applicant, by a lack of understanding and insufficient guidance from regulators during the pre-application process, or by an applicant's decision to withhold information due to product data protection concerns. We will discuss product data protection issues in detail later.

Both regulators provide pre-application advice and guidance to help improve application quality, but due to resource constraints, science advancements and evolving international expectations, there may be challenges in maintaining sufficient guidance for applicants. In many cases, to maintain alignment and save time, the regulators rely on the guidance of overseas regulators, but this can appear patchy and inconsistent to regulated parties. In other cases, the guidance across the EPA and NZFS can appear to be inconsistent or contradictory to applicants. This causes further frustration and confusion for regulated parties.

The provision of additional data once assessment has already begun can cause significant delays to the approval path. This new data must be assessed, and in many cases the risk assessment process repeated to consider the new information. Where new data needs to be generated specifically for New Zealand conditions, the generation of data, including undertaking trial work, takes time and lengthens the end-to-end process. We are not able to comment on the timeliness and rationale of additional data requirements in the middle of assessments (or reassessments) of some products as it requires technical expertise. However, we note with the two processes, the total processing time can be extensive.

3.1.4. Impacts of delays and uncertainty

Many stakeholders and submitters expressed that the lengthy process and uncertainty of when a decision can be expected have caused significant impacts on the industry and in future may exacerbate New Zealand's competitive disadvantage mentioned in Chapter 2.

This may contribute to preventing manufacturers and importers from bringing new and innovative products to New Zealand because it is challenging to plan their business, and the waiting time makes returns from their investment less attractive. *"Without firm timeframes from EPA/ACVM, it is very difficult to plan a supply operation."* (E86)

An independent report also comments on this uncertainty and notes its potential impacts on the EPA's reputation: *"Applicants may have invested large amounts into research and development of the hazardous substances, and time delays (assuming the substance will eventually be approved) will push out their opportunities to recoup those costs. These costs will be passed onto end-users and may, over time, influence market-entry decisions for multinational manufacturers."* (Loan et al., 2023, page 31)

The current state can also discourage research and development activities for innovative technology. Developers may choose to launch their products in other markets which are larger, perceived to be faster (because of their single process) and more transparent and certain than New Zealand's.

One submitter noted:

"Level of trust in the system is very low. We don't trust regulators have the resources …, mindset, processes, … to deliver these outcomes in a timely manner … it has directly affected the willingness of our global company to continue investment into NZ agriculture." (E86)

The flow-on effects are that end users cannot access some products, which may contribute to suboptimal productivity, less competitiveness in international markets and undesirable impacts on the environment. In the absence of new and innovative products, end-users may have to continue relying on old, potentially higher-risk chemicals. Appendix 2 includes examples of limited access to products because of different reasons, including suppliers' commercial decisions and regulatory barriers.

Another impact is that animal welfare might be compromised as some useful veterinary medicines are not available. Without timely and appropriate tools, biosecurity risks may not be effectively managed resulting in the entrenchment of pests and diseases and potentially further economic, social, environmental and cultural impacts. There were concerns that the length of time to receive a decision on an application and the limitations of emergencies provisions under the HSNO Act can cause delays in access to important biosecurity tools. MfE and the EPA are aware of issues with the emergency provisions under the HSNO Act and amendments to the Act or practice may be

needed.[30] This is discussed further in Chapter 5. Early access to products used in responding to some biosecurity incursions is even more critical because with the passage of time, pests or diseases can become more difficult and costly to eradicate or manage.

We note the EPA information that 10 applications under the special emergency provisions were made between 2006 and 2013 and these were decided between two to 19 days with the majority less than 10 days. No such applications have been received since 2013, indicating the existing pathways are functional however would likely still benefit from modernisation.

The opportunity costs of manufacturers, importers, and end users not being able to introduce and use new and innovative products and their various uses can be substantial. Applicants reported in confidence that the time waiting for approval can cost manufacturers and importers millions of dollars in potential sales, far exceeding application fees. We will discuss quantitative impact assessments of limited access to products in Chapter 4.

The application timing and uncertainty experienced by the sector is the outcome of several underlying causes. Stakeholders, submitters and regulators noted an issue relevant to the insufficient resources for regulators to manage their workload. We will discuss other issues and causes in the following sections.

3.2. The approval path split across the two systems introduces complexity

Unlike Australia, applicants of some agricultural and horticultural products in New Zealand must apply to two regulators for approvals, the EPA and NZFS. Applicants must follow two different processes under two regulatory systems with different purposes and approaches to risk management.

The two systems also manage risks relevant to other regulatory systems such as biosecurity, health and safety at work, food safety and animal welfare. This was a legislative choice to ensure effective risk management, with anticipation of some complexity and inefficiency. There are legislative measures in place to mitigate the interface issues (for example, the ACVM timeframes as discussed in section 3.1). During the implementation of this legislative choice, interface issues have manifested themselves in practice, causing regulatory burden to applicants and end-users, which reported in submissions and during the Review's engagement process. This is particularly impactful for novel products with new active ingredients.

As described in Chapter 2, if a product contains a hazardous substance or new organism regulated under the HSNO Act, ACVM registration of that product cannot

[30] The definition of a biosecurity emergency under section 46 of the HSNO Act does not support the use of special pathways for emergencies in biosecurity. This and the 'special emergency' under section 49B of the HSNO Act may create confusion with a biosecurity emergency under section 144 of the Biosecurity Act 1993, which has specific criteria, and enables specific emergency powers. It is likely that emergency provisions are not working as intended to enable access to products needed urgently such as in a biosecurity response.

be finalised without a relevant HSNO approval. All products that are deemed hazardous substances require some form of HSNO approval – either through individual approvals or under a HSNO group standard. Once HSNO approval is issued, ACVM has five working days to align controls with HSNO approval and notify the registration. Some submitters said the interface causes issues for them as detailed below.

3.2.1. Alignment of controls and label approval

The two systems have different approaches to managing product labels. NZFS requires data on efficacy to manage product risks, namely biosecurity effectiveness, animal welfare impacts, trade and public health risks from residues of products. The EPA does not approve labels but assesses *application rates and frequencies* in relation to managing the risks to human health and the environment.

Requirements for labelling are primarily set by the EPA labelling notice[31] plus specific controls relevant to the individual substance.

If applicants need to change application rates to meet HSNO requirements (for example, managing risks to the environment) and the rates are different from the use that MPI has assessed, then NZFS needs to reassess the product. This may involve considerable work and, in some cases, may not be realistic to complete in a very short timeframe set by the ACVM Act (five working days). Or if the application rate of a product needs to increase to achieve the effects claimed in the label approved by NZFS and that rate is higher than what is permitted to be applied by the EPA controls,[32] the product may need to be reassessed by the EPA. One submitter noted *"The specified use restrictions for products set by both ACVM and EPA can be incompatible."* (CS67)

While the need for reassessment to align controls can sometimes be out of each regulator's control, the impacts on applicants can be significant. Submitters reported that applicants also experienced issues of ACVM approved labels containing incorrect EPA-related information. The regulators were of the view that this is the applicant's responsibility, and they need to be aware of and manage this risk from their end. However, if regulators solely focus on their core responsibility and do not pay sufficient attention to the interface of controls set under the two systems, the process is adding regulatory burden on applicants. Good regulatory practices require regulatory agencies to collaborate and help manage regulatory gaps or overlaps and minimise regulatory burden on regulated parties.

Another interface impact is applicants' and end-users' experience with off-label uses.[33] ACVM allows off-label uses if the uses meet the default MRL of 0.1mg/kg. Many growers adhere to Good Agricultural Practice (GAP)

[31] Consolidated Hazardous Substances (Labelling) Notice 2017 | EPA

[32] There are cases where efficacy and/or residue data is still being collected in trials when EPA assessments have already begun.

[33] Off-label uses mean using a product for another purpose/crop which is not specified in the label.

assurance schemes to help manage this type of residue risk. However, the product uses must also comply with EPA label controls, including maximum application rates. If a product is used for a minor crop or minor use[34] and that use is not specified in the label, while that use can meet the MRL requirements, it may not meet EPA controls and off-label uses become impossible.

> *"As EPA becomes more prescriptive in the controls they put upon the use of products, this will prevent the smaller horticulture sectors from utilising products off-label"* (E94).

Some stakeholders were concerned about New Zealand's default MRL, which can be higher than the MRLs set for some products or uses of products registered in other jurisdictions.

As discussed in Chapter 2, many of the crops that New Zealand farmers grow and export are considered minor crops internationally. Due to the costs involved in generating data for these crops, suppliers may not be commercially incentivised to seek approval and registration for uses of these crops, including proving a higher MRL than New Zealand's default MRL is safe for those uses. This presents a challenge for New Zealand end-users and creates pressure to use products off label. Off-label uses are effectively not possible when they cannot meet the default MRL requirement or the EPA's label controls. The EPA has advised that they assess what applicants supply in the GAP tables and HSNO assessments do not require efficacy data. This suggests a possibility to address stakeholders' concerns relevant to the HSNO process. We are not able to comment on controls placed on specific products or for specific uses, but believe discussions between industry and regulators, and between product suppliers and end-users may help address this issue. We will discuss this in detail in Chapter 5.

The two approaches to label controls taken by two regulators creates an impression among some submitters that the two systems are inconsistent. Our view is that this is an outcome of a product being managed by two regulatory systems with different purposes and complex interface and no legislative or formal requirements for coordination between the systems. New Zealand's competitive disadvantage of producing minor crops also contributes to this situation. This interface introduces complexity to applicants and end users, requiring them to understand the alignment of controls imposed by each regulator and their impacts on applications and uses post approval. Some submitters suggested a single regulatory system and single regulator may address these issues. We consider there would still be a need to align controls for managing different risks if agricultural and horticultural products were managed by one regulatory system. However, applicants and users could have better experience if they only had to work with one regulator.

[34] A "minor crop" includes crops other than wheat, canola, barley, soybean, and corn. A "minor use" of a pesticide refers to the crop-protection treatments usually used on low acreage, high-value crops, or, where pest control is only needed on a small portion of the overall crop acreage.

3.2.2. Ensuring product data protection

Data protection prevents the regulator from using protected data to assess other applications to register similar products during the protected period. Manufacturers highly value data protection because it prevents subsequent applicants from free riding on the costly research and development of the original applicant. Data protection significantly influences their commercial incentives to enter a market and engage with a regulator, as a competitor registering a competing product based on their data would be a significant loss of competitive advantage.

The two systems have a complex interface relevant to product data protection. The ACVM Act provides product data protection for innovative and non-innovative TNP for ten or five years after the registration decision, respectively. The HSNO Act does not provide product data protection directly to all HSNO applications but applies the ACVM requirements of product data protection if the application is for a product that is or has been subject of an innovative TNP application.

Applicants who want protection will first apply to NZFS, sometimes with incomplete applications, before applying under HSNO. This creates inefficiencies by adding to the ACVM queue with applications that cannot be processed and delaying applications that are ready for assessment. Alternatively, an applicant may delay applying to the EPA until their full application is ready for NZFS. This means they will miss the opportunity to enter the EPA queue or be assessed by the EPA when the application is already ready for HSNO assessment.

Some submitters suggested existing data protection under ACVM be extended. Data protection can limit competition, and slow down registration of more affordable generic products. It means during the protection period, applications of generic products need to be assessed in detail, rather than 'in reference' to an existing approval or authorisation. There is a balance between encouraging innovation and enabling competition. We consider that the current ACVM data protection provisions strike an appropriate balance and are comparable with data protection provisions in Australia.[35]

We also heard about some concerns regarding "*how data/IP is handled within and across regulators. This will be an important element to get right for investor confidence*" (E105) and how the EPA manages confidential information. We received the EPA's advice relevant to their guidance on confidential and commercially sensitive information. MPI also has policies and protections as required by relevant legislation. We understand that the EPA has recently strengthened their management of confidential information provided to them during a call for information before lodging a reassessment application. Regarding the mechanism to ensure product data

[35] Canada: 10 years for new chemical registrations (can be extended to up to 15 years through additional uses). The EU: 10 years for innovative registration, 10 years for non-innovative registration. Australia: 10 years for a new active ingredient, 5 years for a pesticide with existing active ingredients, and 3 years for veterinary medicines with existing active ingredients. Some other countries operate 'compensable' schemes, where subsequent applicants have to pay the original data holder for the right to use data (Ministry for Primary Industries, 2016).

protection, both agencies are following legislative requirements within the confidential product protection periods. Notifying information to certain government agencies, including across the EPA and NZFS is also being regulated by the ACVM Act.

3.2.3. Additional interface issues

There were concerns about the two regulators requiring the same data. We have verified this with agencies and understood that there is some overlap, for example information on physical-chemical properties. Sometimes the same data is required for different risk assessments.

Some submitters found that the ACVM Act is less prescriptive, allowing for more interpretation, while the HSNO Act is more rigid, for example requirements on application forms under section 28 of the HSNO Act and section 10 of the ACVM Act. However, we consider both pieces of legislation provide sufficient discretion and flexibility to regulators in managing relevant risks. The EPA was also seen by some stakeholders as placing less priority on responding to industry's needs than NZFS. The EPA was perceived as more conservative to maintain their independent role while NZFS is found as more approachable, while still maintaining their independence.

The design of the approval path across the two systems also means differences in the areas of regulators' specialist technical knowledge, and this expertise may not be shared to its full potential. For example, NZFS has greater understanding of on-farm practices and pest management, and the likely benefits of products, which may be useful for the EPA in understanding the likely effects of a substance being unavailable.[36] The EPA has greater toxicology expertise, which submitters have indicated could be useful to NZFS when considering changes to formulations.

3.2.4. Overall comments on the interface issues

Agricultural and horticultural product applicants need to prepare **two** applications and follow **two** screening processes (pre-application), **two** public consultation/notification processes (for complex applications),[1] **two** decision-making processes and notification periods.

This places additional regulatory burden on applicants and end users. We consider that the historical design of the approval path, which involves two regulatory systems having different purposes and approaches with limited collaboration between regulators result in overlap, inconsistency and complexity.

The current legislative design ensures the HSNO system manages environmental and safety risks while the ACVM system manages other risks. Therefore, we do not consider that one regulatory system would provide overall benefits (we will discuss in detail in Chapter 5 and Appendix 3). However, acknowledging the interface, its

[36] Under section 29 of the HSNO Act, the EPA is required to take into account the likely effects of a substance being unavailable.

complexity and impacts on applicants and end-users as an outcome of the design is important if New Zealand chooses to continue this design.

We acknowledge the additional complexity caused by the interface between ACVM, HSNO and other regulatory systems. However, we have not analysed this in detail as the scope of the Review is focused on the interface between HSNO and ACVM.

3.3. There are efficiency concerns relevant to the approval path

3.3.1. New Zealand is not using overseas regulators' assessments to the fullest extent

As New Zealand is usually not the first market for launching new agricultural and horticultural products, there are opportunities to use information and assessments from overseas regulators to facilitate assessment processes.

Many submitters asked for better use of international information for different types of products. Regulators both in New Zealand and overseas already use information from other regulators to improve efficiency. Any opportunity to further improve efficiency and make use of work already undertaken by other regulators (where appropriate to New Zealand) would enable our limited resources to be used more efficiently.

While the HSNO Act enables the EPA to use relevant information, including from overseas regulators, they are required to review or verify it.[37] Following amendments in 2022, there is a rapid assessment pathway, which explicitly includes reference to using overseas regulators assessments and decisions. This pathway cannot be used where the EPA considers the application will have *"significant cultural, economic, environmental, ethical, health, or international effects"*. The regulator believes it is challenging to determine there will be no significant effects if the active ingredient has never been assessed with any consideration of the New Zealand context. While the 2022 amendments are still being implemented, and the full benefits have yet to be realised, we consider that the legislative amendments do not fully capture the initial intent of the pathway.

The ability to rely on international regulators' assessments was originally intended through the 2022 HSNO Act amendments, as can be seen in proactively released Cabinet papers. It was intended that how the EPA relies on international information would be detailed in the Hazardous Substances and New Organisms (Methodology) Order 1998 (Ministry for the Environment, 2020 & Ministry for the Environment, 2021). However, through the drafting and Parliamentary process the scope was narrowed as some stakeholders were concerned that the original drafting

[37] Section 20, Hazardous Substances and New Organisms (Methodology) Order 1998.

could form the basis for the pathway to become a "rubber-stamping" exercise.

> We believe the EPA could rely more on international regulators' assessments while still undertaking assessment of matters specific to New Zealand.

Our view aligns with the Parliamentary Commissioner for the Environment's comment during the select committee process for the 2022 HSNO Act amendments: [the proposed amendments] "*could limit the EPA's use of up-to-date international information.*" We consider that while the EPA can and does make use of international information, there is likely value in providing clarity that it is the law makers' expectation that the EPA relies on international regulators' information and assessments where it is appropriate to New Zealand. It is important to clarify how the EPA can rely on this information for other assessment pathways and how it must be undertaken differently from the current practice to improve efficiency and transparency. It is also important to understand which applications are likely to have *"significant cultural, economic, environmental, ethical, health, or international effects."*

Currently, the only explicit pathway for NZFS to use overseas regulators' information is the Registration by Reference to the APVMA for veterinary medicines for non-food producing animals. Under this pathway, NZFS uses the APVMA reports in lieu of external data assessment. We consider there is an opportunity for NZFS to make better use of international regulators' work, where appropriate for New Zealand.

3.3.2. International engagement can be further improved

The uses of approved products in New Zealand can be restricted by the MRL requirements of countries importing New Zealand's exports. Given the primary sector's heavy export focus, international engagement to support realistic and evidence-based MRLs is critical to enabling meaningful access to products.

Both the EPA and NZFS have engaged at the international level to adopt best practice, harmonise requirements and improve efficiency. For example, utilising toxicology and environment data package in multiple countries. International engagement also supports label harmonisation. Some submitters expressed their expectations for more international alignment in ACVM labelling, especially with Australia, which could save significant time and resource for them.

NZFS has undertaken some joint reviews with international regulators, to collaborate simultaneously on authorising a product. This can reduce the burden on applicants and improve access to products. The EPA has not participated in a global joint review in at least the last 10 years, due largely to resource constraints and that the direct benefits of participation are less apparent for an HSNO assessment than an ACVM assessment. This is because global joint reviews can support mutually set residue definitions and limits, which support trade flows, and global joint reviews for environmental risks are generally limited to determining end points, which the EPA can incorporate

without directly participating. Given that manufacturers typically bring products to New Zealand much later than other jurisdictions, it may not be efficient for the EPA to commit resources to reviews for products that might not be registered in New Zealand.

We note that all jurisdictions and regulators will have different priorities and ways of managing risk, and it would not be reasonable to expect everything to be exactly the same. It is natural that some areas are not able to be harmonised. This likely links to areas where stakeholders and submitters reported regulators asking for information that went above and beyond what other regulators requested or was inconsistent with international practice. However, we consider there is room for more international engagement, including considering what jurisdictions or markets are of most value for harmonisation.

3.3.3. Regulation of some products is disproportionate to the level of risks

The two systems already provide proportionate risk-based management approaches through group standards, rapid pathway assessments, exemptions from registration, and self-assessments. However, these tools have not been fully used to ensure the proportionality of regulation.

Proportionate efficacy and residue assessment for some products

Submitters expressed concerns about proportionate data requirements for some products, for example, biologicals, which can delay the assessment process. In addition to using efficacy data to manage risks, the ACVM system is currently also assessing efficacy to ensure claims made in the label are accurate. Applications with general, qualitative claims (such as 'aids in the control of x', or 'reduce methane production') have lower efficacy requirements than specific, quantitative claims (such as 'treats x', or 'reduce methane production by x% per y'). There appears to be inconsistent understanding of this amongst applicants. While some applicants wish to generate the data required to verify specific claims for commercial reasons, others may not understand the efficacy assessment requirements and were frustrated when required to provide efficacy data for their specific claims.

ACVM assessment also means that applications for broad scope often require more efficacy and residue data than ones for narrow uses,[38] for example, "used for kiwifruit" vs "used for kiwifruit, grape vines and berries". To manage the amount of data that needs to be provided, some applicants apply for a narrower scope, with end users using the products off-label instead. This may lead to a misalignment of controls with the EPA approval as discussed above.

Proportionate management of lower risk products

There are opportunities to improve the proportionality of the system by reducing

[38] We note, in some cases, it is possible to extrapolate efficacy data from one crop to others.

regulatory requirements for lower risk products or keeping regulations more adaptive to innovation and changes. This is a legislative expectation provided under section 76 of the ACVM Act and section 96C (1) of the HSNO Act. Agencies are aware of this need and are making improvements in some respects as mentioned below. Insufficient resource and competing priorities for maintaining effective regulatory stewardship can create some challenges, particularly the speed at which changes to the system can be made.

Biologicals

Stakeholders and submitters raised their concerns around disproportionate management of some groups of products. As discussed above, applicants of biologicals, including biopesticides can sometimes struggle with ACVM efficacy assessment and data requirements.

Biological based products (commonly referred to as biologicals) are a broad category of products derived from natural materials, such as animals, plants, bacteria or fungi. They differ to conventional products, which are made from synthetic chemicals.

While biologicals have been available for decades, there has been increasing focus and end-user' demand for these sorts of products in recent years. In some cases, biologicals can be low risk, for example, low hazard biopesticides, but some products can have human health risks that need to be managed, for example, immunotherapeutics or vaccines. They are not always a direct replacement for chemicals as a single tool but can be particularly useful as a part of Integrated Pest Management.[39] They often have lower efficacies than chemicals. Some submitters report that the registration process appears to require efficacy of biologicals similar to that of chemicals. Some applicants are also expecting to make similar claims to traditional products.

NZFS recognised the need for proportionate assessment and appropriate guidance for biologicals, for example, proper label messages. The regulators agreed that some technical adaptations can be taken, particularly to the data requirements, to make them more suitable for biologicals.

We note that since biologicals can contain a new organism, the importation of those products would require a good understanding and navigation of the complex interface between the HSNO, ACVM and Biosecurity legislation.

Inhibitors

Applicants for environmental inhibitors have also commented on the burden of regulatory requirements from the ACVM system. Inhibitors are agricultural compounds that are intended to decrease the harmful effects agricultural activity can have on the environment or mitigate the

[39] Integrated Pest Management is the consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations. It combines biological, chemical, physical and crop specific (cultural) management strategies and practices to grow healthy crops and minimize the use of pesticides, reducing or minimising risks posed by pesticides to human health and the environment for sustainable pest management (Integrated Pest Management (IPM) | Pest and Pesticide Management | Food and Agriculture Organization of the United Nations | IPM and Pesticide Risk Reduction | Food and Agriculture Organization of the United Nations).

effects of climate change. They primarily include methane inhibitors and urease/nitrification inhibitors.

Inhibitors are a relatively novel product, which has only recently been incorporated into the ACVM regulatory system, and an area of strong demand for new products. Adverse events like the 2013 dicyandiamide (DCD) milk contamination incident, have highlighted the potential risks and impacts that these products can pose. To manage these risks, these products were brought into the ACVM regulatory system in 2022, in large part due to the concerns of major exporters that increased use of these products to meet climate targets could adversely impact trade without appropriate regulatory oversight.

Inhibitors are very different to other ACVM products and incorporating them into an existing regulatory system has posed challenges. One key challenge has been the differences in relation to efficacy. Our understanding is that it is more challenging to quantify the impact of inhibitor products. As efficacy is not directly visible to end users, this changes the incentives for how end users use the product, which can reduce the risk of residues.

Given these are relatively new products, international regulators have differing approaches to their use. New Zealand is one of the first countries to regulate inhibitors, in part due to our heavy agricultural export focus, the contribution that agricultural emissions have on New Zealand's overall emissions profile, and the disproportionate impact that trade disruption will have on the economy.

While other countries, such as Australia, are not regulating inhibitors under their agricultural and veterinary chemical regulatory system, inhibitors currently require registration under ACVM, and some require both HSNO and ACVM management. We understand that there are concerns about public health and trade risks from inhibitors' residues which warrant government oversight. However, there is room for facilitating or streamlining the assessment process.

Inhibitor and HSNO group standards' process

One stakeholder expressed concerns about the current process for amending HSNO group standards to include inhibitors. The EPA advised that inhibitors are a broad group of substances with different characteristics and risks across substances.[40] Some inhibitors can fit under certain existing group standards and the EPA is working on guidance to clarify those scenarios. Other inhibitors may require amendments to existing group standards which includes public consultation. However, where there is a clear rationale to amend an existing group standard the process can be straight forward. If development of a new group standard is more appropriate, the EPA can work with industry to develop that group standard. The EPA also noted that as inhibitors are a new, evolving type of substances, there is not a significant history of similar substances being approved under HSNO or

[40] For example, the risks to the environment will be very different for a hypothetical inhibitor applied in a wide-spread manner to pasture versus something administered directly to an animal.

assessed overseas by recognised regulators. We expect future HSNO assessments will be proportionate with the risks of those inhibitors.

Animal feed

Some submitters felt that NZFS interprets the ACVM Act in a way that places unnecessary burden on industry and restricts access to the animal feed market. Their views were that animal feed making certain types of 'animal health claims' should be exempted from registration. We note that feed that claims to have a medical or therapeutic function must be registered under ACVM because of animal welfare impacts if the supplemented feed is not efficacious and delays effective medical treatment. Our view is that it would be reasonable to exempt products that are marketed solely as feed for non-food production animals (for example, companion animals and equines).[41] We note that some jurisdictions, like Australia, have approaches for this which could be considered.[42] MPI is currently considering this issue and what changes may be needed to the ACVM regulations.

Treated seeds

Treated seeds are an issue some stakeholders and submitters focused on. Treated seeds are seeds that have been coated with a hazardous substance, such as a pesticide, to prevent damage from pest species before or after planting. As the EPA has consulted on a proposed new group standard for treated seeds, we expect that the EPA will consider submitters' concerns regarding any additional regulatory burden or restrictive conditions of the standard compared to other jurisdictions.

Low risk applications

Some stakeholders wanted more flexibility in assessing low-risk applications, for example, *"if a company is reformulating a product that has already been assessed and approved, and the way the product is used is the same, the hazard classifications are much the same, or better, this should be a more streamlined, simple process which industry feels is not currently the case"* (E105). The EPA advised that the rapid assessment pathways under the HSNO Act already provide for such cases and the EPA is using these pathways to reduce the queue where appropriate. The ACVM Act does not provide for a rapid assessments process but reliance on confidential information of approved products is possible after the product data protection period. Within the protection period, the applicant who has the data protection, can allow the regulator to use their data to support another company's application.

[41] We note horses were processed for human consumption in New Zealand in the past but not currently and at a very small scale.

[42] Animal feed products | Australian Pesticides and Veterinary Medicines Authority

3.4. There are significant concerns relating to regulators' resources, tools, and engagement

3.4.1. Regulator capacity and resourcing

Apart from efficiency concerns mentioned in section 3.3, we believe resourcing is a key issue affecting the current state of the approval path. We will discuss issues with using industry knowledge in the engagement part of this section and resource prioritisation in section 3.5.

While one submitter noted that *"ACVM needs to be well-resourced (funding, people, IT infrastructure) to maintain approval timelines…."* (E84), there was significantly more feedback on the EPA's resourcing issues. Feedback from end-users, exporters, environmental stakeholders, and public health experts was more specific on the EPA resources while that from manufacturers and industry bodies was relevant to the EPA's capacity and capability in general. This section, therefore, will focus more on these.

The EPA resourcing

Recent reports noted that "*the EPA is not funded to process the volume of applications it receives in a timely manner"* and the EPA is under-resourced compared to equivalent overseas regulators (Loan, et al., 2023 and feedback from public health and environmental submitters). The EPA is primarily funded by the Crown and fees/charges recovered from applicants. Independent reports have indicated that the EPA uses Crown and cost-recovered funds effectively and efficiently (Martin Jenkins, 2022; Loan, et al., 2023). However, some stakeholders disagreed with this and believed inefficiency and prioritisation were the key drivers of the current state of the approval path. They were concerned about "*the EPA's overly intensive oversight/sign-off process for 'simple' applications"* (E105) and that past performance was more efficient than current. We note other stakeholders asked for more robust decision-making processes, including using external peer review services. We have not investigated the HSNO decision making process in detail and if existing funds and resources have been used in the most impactful manner for increasing the speed of assessment decisions, as this requires technical expertise. However, we discuss efficiency in section 3.3, resource focus and prioritisation in section 3.5.

The EPA's cost recovery levels are lower than domestic and international regulators that deliver similar regulatory functions, such as ACVM or Medsafe New Zealand, or the Australian Pesticides and Veterinary Medicines Authority (APVMA) (Loan, et al., 2023) and the Australian Industrial Chemicals Introduction Scheme (AICIS). The EPA is currently recovering around 23% of application costs, ACVM fully recovers registration costs through fees, charges and levies (Ministry for Primary Industries, 2024d). Medsafe New Zealand recovered ~88% costs from industry in 2021/2022 (Ministry of Health, 2021). APVMA recovers approximately 40% of application costs through application fees, with the remaining costs recovered through annual levies, bringing the cost

recovery level to around 95% (Australian Pesticides and Veterinary Medicines Authority, 2024a). AICIS is fully cost recovered (Australian Industrial Chemicals Introduction Scheme, 2024).[43]

The EPA has lower total costs per complex application assessed than overseas regulators (Loan, et al., 2023). It is relevant to note that the costs, nature and scope of EPA functions and HSNO approvals cannot be directly compared to other regulators, as there are relevant differences. For example, there are two assessment processes for some agricultural and horticultural products in New Zealand. We also note the most complex application for approval from APVMA (whose approval is equivalent to both HSNO and ACVM) would cost the applicant 116,501 AUD (approximately 128,000 NZD in 2024), in addition to a tiered annual levy based on product sales. In New Zealand, the most complex application would likely cost approximately 45,854 NZD[44] in addition to an annual ACVM levy of 1,132.75 NZD.

The current EPA cost-recovery levels from industry may not adequately reflect the benefits that manufacturers, importers and end users receive from approvals, and the role they play in creating and exacerbating the risks that require regulatory management and the administrative costs of regulation.

Despite the HSNO Act enabling the EPA to recover the actual and reasonable costs incurred in the exercise of its functions, power and duties (section 21), historically the EPA has recovered a small proportion of the costs from applicants. This stems from a Cabinet decision in 2003 which considered an incentivisation for bringing new products to New Zealand, the existence of a free rider effect, and a recognition of the public benefits associated with approvals.

While some of the detailed justifications remain valid today, others would warrant re-evaluation given changing circumstances and updates to government cost recovery principles over the last 20 years. A review may support changes to the percentage of costs to be recovered. Re-examination of the HSNO cost recovery rates was recommended in 2014 (Ministry for the Environment, 2015). This happened in 2018 and 2023, however, they only increased from ~11% to ~23% of the application costs.

While New Zealand's small market size may justify Crown funding to encourage access to innovative products, given Crown funding is being used for a service that delivers commercial benefits, it is important to review this regularly. This includes assessing if the objectives of cost recovery have been achieved. Representatives of some end users and exporters stated, *"In principle, … support the costs of managing registrations being fully recovered from the registrants."* (E102). Environmental stakeholders' view was that

[43] 2. Policy and statutory authority to charge (cost recover) | Australian Industrial Chemicals Introduction Scheme (AICIS); 3. Charging (cost recovery) model | Australian Industrial Chemicals Introduction Scheme (AICIS).

[44] EPA complex applications cost 27,500 NZD. NZFS charges assessment rates at 262.20 NZD per hour, with the average assessment time for a new active ingredient application being 20 to 30 hours (5,244 to 7,866 NZD), with the high-end estimate for the most complex active ingredient application being 70 hours (18,354 NZD). Therefore, the high-end estimate for a highly complex new application would be 45,854 NZD.

"Section 21 of HSNO empowers the EPA to recover the actual and reasonable costs … why this power has not been used to properly fund the approval processes of the EPA, particularly in the context of hazardous substance approvals that confer significant private benefit" (CS39). One independent report noted that there is "*no evidence that applicants are highly sensitive to price and will be deterred from introducing new products to New Zealand if their applications do not continue to be subsidised*" (Loan, et al., 2023, page 39).

While a small number of submitters supported increasing the EPA's costs recovered from industry (and Crown funding) for updating EPA risk assessment models and retaining staff, many others expressed concerns about its financial impacts on end users and disincentivising registrations, especially when the industry is facing other financial challenges.

We have observed that some regulated parties have limited trust in how regulators use industry funding. Stakeholders raised concerns about recent ACVM cost recovery increases, including how industry funds are used for wider projects such as *"complex information systems"* (E105). NZFS advised that the 2024 increases in ACVM fees was partly to balance the deficit accumulated in previous years which resulted from the decreases in fees in 2019. ACVM cost recovery is not only used for assessments, but also for other regulatory functions that support ACVM registration. Some of the cost recovery increases should support NZFS improve assessment quantity and quality, which will take some time to demonstrate the improved outcomes. We note the increased cost recovery rate had only been in place a month at the commencement of this Review.

We also understand that NZFS investment on an online system is in response to industry request for a self-service portal, which will provide increased transparency on application status, and reduce administrative time and costs both to regulated parties and NZFS. NZFS engaged with KPMG to identify opportunities to improve the efficiency of the ACVM assessment process (KPMG, 2022). NZFS is implementing KPMG's recommendations, which include increased staff training, recruitment and retention, and technology improvements. We consider it is reasonable for industry to expect transparency in cost recovery, and it is important for industry and regulators to discuss industry funding and its efficient use.

Stakeholders' concerns highlight the importance of undertaking a robust cost recovery analysis and a policy process following the Treasury's and the Office of the Auditor-General's guidance on cost recovery principles, namely transparency, justifiability, efficiency and equity. As the EPA has recently increased HSNO application fees from 01 August 2023, stakeholders expected to experience improvements for agricultural and horticultural products before any further increases are proposed.[45] Best practice for cost recovery is to undertake it in an 'open book' manner, and with meaningful consultation, providing the opportunity for

[45] Although we note this review was focused on inflation adjustments.

stakeholders to contribute to the policy and design of the cost-recovered activities. Given stakeholders' concerns about funding efficiency, this issue should only be addressed along with other efficiency and transparency issues, and rebuilding trust and confidence between parties.

We also note other HSNO functions that are directly relevant to the manufacture, distribution and use of agricultural and horticultural products but are currently fully funded by taxpayers, for example, group standards, engagement, guidance, or monitoring and enforcement. Other domestic and international regulators recover these costs through annual levies, which are not available under the HSNO Act.

3.4.2. The EPA risk assessment models are outdated and no longer fit for purpose

As part of its risk assessment for some substances, the EPA quantifies the risks posed by hazardous substances to human health and the environment using risk assessment models (toxicological, ecotoxicological, and environmental fate (e-fate) models).[46] For this purpose, expert technical assessors employ models to simulate application and exposure scenarios that would occur in the real-world to predict potential effects. This helps assess risks and determine appropriate controls (where applicable).

> The risk assessment models used by the EPA to assess applications of hazardous substances are no longer fit for purpose.

Some of the e-fate models used by the EPA are screening tools that offer limited or no ability to move through a tiered approach.[47] This means the regulator cannot provide realistic estimates for determining exposure in a New Zealand context. The use of these outdated tools and/or worse-case default values results in outputs that may over-estimate the risks (and in some cases, underestimate the risks). This may lead to inappropriate risk management measures, for example, too precautionary controls and limitations on products. An unintended consequence is newer, potentially more effective products or technology may have greater controls than those for existing older approvals which were transferred to the HSNO system in the 2000s and have yet to be reassessed due to resource constraints.

In the hydrogen cyanamide (Hi-Cane) reassessment, industry had a range of

[46] Toxicological models help predict impacts on people, including operators, workers, and bystanders/public. Ecotoxicological models inform potential impacts on terrestrial and aquatic organisms/species. E-fate models help predict the environmental concentrations and effects of the chemicals in soil, water, and sediment.

[47] The concept of a tiered approach in risk assessment is that the first tier is usually simplistic and conservative and is used as an initial screening level. If a substance fails the risk assessment at this tier (the predicted level of risk exceeds what is considered acceptable), a more detailed risk assessment is undertaken at the next tier. This involves various refinement options to more accurately estimate the level of risk. As assessment moves to higher tiers, the complexity in the risk assessment increases, and the precision ("realism") in the risk assessment also increases (and the level of uncertainty and conservatism decreases).

concerns,[48] and there were different phases in the process with multiple interactions between the EPA and industry. One of the concerns raised was when industry requested the EPA use a newer iteration of the European Food Safety Authority (EFSA)'s bird model. The EPA was unable to do this, as this model is not validated for use in New Zealand conditions. Industry provided a calculation using the newer model for the decision-making committee to consider. However, the EPA disagreed with industry on the relevant choice of bird species used, which leads to differences in model outcome. The decision-making committee reviewed this information and imposed new controls instead of a phased-out ban of the product as initially recommended by the EPA. This process showed the impacts of using older, potentially more conservative risk assessment models, which included repeating interactions with industry and prolonging the assessment process. This experience was stressful and prolonged for the industry and undermined the industry's trust in the regulator.[49] This process shows that there are challenges for the EPA to leverage information, including using newer models, from recognised regulators for its risk assessment because models used by the EPA have been superseded in other countries.

The state of the EPA risk assessment models has been noted in recent reports (Parliamentary Commissioner for the Environment, 2022 & Loan, et al., 2023). The Sapere report assessed that "*the economic consequences for New Zealand from inadequate risk assessment could be significant*" (Loan, et al., 2023, page 33). This issue was raised by different submitters, including industry, end-users, environmental stakeholders, public health, and legal and technical experts.

We also note that the models used by larger regulators (such as, EFSA or United States Environmental Protection Agency (US EPA)) and associated guidance material are publicly available. This enables applicants to conduct their own risk assessments and supports the culture of transparency and trust between industry, the regulator(s), and the public. While the EPA cannot utilise these models directly due to different climate patterns in New Zealand, it would be beneficial to take a similar approach to make updated models public. We note the EPA has previously sought government funding to update their modelling capability, but these bids were unsuccessful.

It is a challenge for regulators (both in New Zealand and internationally) to recruit and retain experts who can interpret studies and perform the models for optimal risk assessment. As small regulators, the competition is even harder for the EPA and NZFS.

[48] These include the prioritisation of this active ingredient over other harmful chemicals in the EPA reassessment priority list, the robustness of grounds for reassessment, the length of the process, the use of dated models, the EPA engagement process, and particularly the application of the precautionary approach.

[49] We note the EPA considered that the process led to a reasonable outcome – the initial concerns regarding carcinogenicity (from a recognised international regulator) and environmental issues could be managed, including with studies from industry to demonstrate safety thereby enhancing social licence.

3.4.3. The independent data assessor model for ACVM can be strengthened

Due to the tight statutory timeframes for making decisions on applications and limited technical resources, ACVM requires all applications to include appropriate data assessment reports from a competent and independent data assessor or request NZFS to undertake the data assessment at a cost. When data assessment works well, this process frees the regulator to focus on the risk management assessment and approval process, while the applicant proves and demonstrates they have completed the relevant risk assessment.

No accreditation is required to be listed as a data assessor, and we have heard from NZFS, end users, applicants, and data assessors themselves that data assessor quality varies. Applicants were concerned that they cannot determine assessors' experience and their services' quality and there was a lack of feedback from NZFS to data assessors on applications. Some submissions noted that due to the variable quality, NZFS is not confident in the assessment reports and will often duplicate the assessor's work by reviewing the data dossiers again in detail. This means the ACVM independent data assessor process may not be fully achieving the intended purpose and providing the efficiency envisioned. The success of the independent data assessor process also depends on sufficient training being provided.

The benefits of the ACVM data assessor process were internationally recognised and recommended for Australia, however it was recommended to be based in legislation (AO, et al., 2021). We note that the Australian Government decided not to accept this recommendation, as they considered improving arrangements for external experts and internal resourcing would better address approval times.

Given the benefits of ACVM data assessor model are recognised by industry, we consider this model can be strengthened, especially in terms of data assessors' role and improving the quality of their services.

3.4.4. Regulator engagement and advice to applicants can be improved

Application engagement and advice

Many submitters expressed the importance of regulator communication, engagement and guidance for their application and the path it would follow as well as where it is in the overall process. Applicants wanted visibility of the status of their application and transparent processing timeframes.

Communication when applications are in the queues

Communication with applicants is needed at all stages of the process. When an application is in a queue, the applicant is eager to know when it is likely to be processed so that they can plan their business. Regulators may think that there is little they can update at this stage and communication with applicants can take away their time which can be used for processing applications. While the resource required to do this needs to be balanced, visibility and clarity on when an application can be expected to begin assessment, or any changes to expected timeframes are greatly valued by applicants. As a part of responding to the applicants' needs, MPI is developing an

ACVM online portal system to better inform applicants of the status of their application.

Applicants also highly value pre-application advice to improve the quality of applications and avoid unnecessary delays due to the lack of information for assessment. The EPA and NZFS advised that they have been offering pre-application meetings for some time and there is a possibility for applicants to directly contact the application lead. This is not always available in other jurisdictions. They also noted pre-application advice and updates require resources.

When in the queues, some submitters said they did not understand what prioritisation was used to progress an application to formal receipt and how they could prioritise their own applications. We understand the two regulators are operating on a first come, first served basis but some guidance about potential prioritisation within multiple applications from one single applicant may be needed. NZFS advised that they provided some guidance on this, for example, in ACVM annual workshops.

Communication once applications are being processed

As the statutory timeframes do not reflect end-to-end assessment processes, regular communication on expected assessment timeframes once applications are formally accepted is important to manage expectations. Communication on the reasons and impacts of requirements for additional information, and the need for alignment in controls set by each regulator are also needed.

More information from both agencies on data requirements is critical as applicants found the requirements are particularly complicated. While NZFS proactive engagement with industry is appreciated by some submitters, others mentioned that NZFS can sometimes be vague about what it needs in an application and has poor communication channels with certain groups (veterinarians).

Engagement with iwi/Māori for the EPA assessment of substances

Submitters also wanted more support in the identification of risks to Māori cultural values. We heard about the EPA's consultation with Māori businesses, but the regulator's proposed controls did not reflect this group's views. One submitter noted that the EPA acknowledged not being able to engage with as many Māori groups as they would have liked for one application. There were also concerns from submitters about *"the requirements of new type of consultation with no clear legislative basis, no clear guidance, and functions that appear overlap regulator duties"* and *"use specific providers for consultation"* (E86).

> The EPA advised that they need to balance different views from different groups and meet the requirements under section 6 of the HSNO Act.

We cannot comment on specific application outcomes, however, this feedback suggests the industry expected improved engagement with Māori and more guidance and explanation from the regulator to applicants.

Regulator engagement in general

Some submitters said both agencies could introduce unexpected criteria, require unnecessary data or testing,[50] change trial requirements without industry consultation, and reject information or data without explanation. We have not been able to verify these claims due to the need to maintain confidentiality of submissions and the inherent nature of different views from different parties as well as expertise required.

We note the sector's general feedback is that they value *"proactive engagement, [good] communication quality and opportunities to incorporate industry feedback early. Strong and early engagement with industry enables understanding of industry systems, builds trust and valuable science expertise to inform risk context and decision making"* (E105). The industry wants *to "support regulators with solutions and expertise (including industry systems, science, risk and business knowledge), but feel opportunities have been missed for meaningful engagement and incorporating their input."* (E105)

Given the substantial feedback on this topic and the flags of "*breakdown of trust*" (E94), we considered there is a need for, and benefits of, improved communication, engagement and guidance from the two regulators. This is especially needed when the application process is lengthy, causing frustration to applicants.

Strategic communications

We noted there are existing engagement forums led by NZFS.[51] Stakeholders were interested in having similar forums with the EPA. NZFS and the EPA also produce monthly newsletters and engage with industry bodies where opportunities open. However, these forums appear to focus on operational matters although strategic matters can sometimes be discussed.

There needs to be a forum for discussions of strategic direction by senior leaders and for the approval path across the two systems, which would enable greater collaboration and transparency between the industry and government. Submitters gave an example of an international practice where industry can engage directly and yearly with government in Australia, Canada and the USA on priority pest pressures and solutions, including gaining access to products to deal with priority pests.

Trust, confidence and performance reporting

The relationship and sharing of information between regulators and regulated parties are critical to ensuring issues and challenges can be promptly identified and addressed. One submitter commented: *"It's fair to say that in recent years, there has been a fundamental breakdown in trust between all parties. The regulators do not trust the manufacturers or the growers, and the industry parties have little to no confidence in the regulators. This*

[50] Such as elemental impurity data, additional validation data for internationally registered products, and trial animal ethics documentation in foreign languages.

[51] Such as the ACVM Industry Liaison Group, the ACVM Advisory Council, the annual ACVM workshop, the ACVM Inhibitor Operational Forum.

situation must change…" (E94). This comment resonates with our observations of the strain in the relationships, particularly between the EPA and industry.

Transparency how industry funding is being used and its outcomes

Stakeholders asked for transparency of how industry funding has been used and its outcomes. As we discussed above in the regulator resourcing section, this expectation is consistent with the transparency principle of cost recovery.

We have also heard concerns from stakeholders and submitters that they are not listened to, despite the existence of existing forums. While we have not been able to verify how their feedback is treated, we noted there are no formal structures or arrangements for industry representatives to contribute with the leaders of each regulatory system in a joined up and cohesive way at a senior level.

It is our observation that the sector' concerns have not always been well understood and sufficiently addressed. In a similar way, some submitters have also misunderstood or been confused in some matters. This has led to a point where there is a break-down of trust and confidence between regulators and some regulated parties.

Some submitters acknowledged recent work undertaken by both NZFS and the EPA, for example, ACVM performance management framework, workshops on ACVM data assessment model, and EPA efforts to address the backlog. While regulators should provide opportunities for issues to be raised, it is also important that regulated parties proactively raise issues and have appropriate forums to do so.

3.5. There is currently no common strategic approach to the approval path across the two regulatory systems

3.5.1. Strategic outlook

As part of effective regulatory systems, there needs to be a clear strategic approach to the approval path across the two regulatory systems, which is critical to support primary industries achieve the goal of doubling exports by value in 10 years (Ministry for Primary Industries, 2024c). It is also important in a context where farmers, growers and other primary industry users are facing increased biosecurity risks and challenges in responding to climate change and animal welfare issues.

We acknowledge that each regulatory system has its own leadership, governance and strategy in place. It is important to note that many novel agricultural and horticultural products need to interact with two regulatory systems, and there is no oversight of the approval path as a whole for these products. With the lack of the oversight, issues have arisen and have not been addressed in a timely manner.

If the design of an approval path across two regulatory systems is to continue, oversight of the approval path is needed. While there are some measures in legislation to mitigate the impacts of the design, this understanding is even more critical at an operational level. Over the course of this Review, we observed two agencies with different strategies, governance arrangements, approach to engagement, and response to issues raised. While differences are to be expected between agencies (and were in part envisioned when separating the functions), we consider it is likely that the magnitude of these differences has contributed to the challenges faced by applicants navigating both regulatory systems.

While ensuring the effectiveness of risk management is the primary purpose of the regulatory systems, this must be done in the most cost-effective way. Regulation should not add unnecessary barriers to New Zealand's agricultural competitiveness. We believe this understanding is not fully embedded in some parts of the systems and industry are well placed to support this. We also note, there is currently no cohesive single strategic outlook and an appropriately senior forum for discussing matters relevant to agricultural and horticultural products from a New Zealand Inc perspective. Any significant changes to risk management should include broader perspectives, including Treaty partners' views, environmental, public health and public concerns.

Horizon scanning is important to enable end-users access to new products and innovation. Biologicals, inhibitors, and new veterinary medicines are changes that need regulatory responses, but existing responses to address these changes have been slow. New Zealand regulators need to be agile and innovative to be able to respond to evolving practices and regulated environments – New Zealand cannot afford static regulation. New pathways of registration or approval need to be considered and adopted.

Industry is likely to hold the information most relevant to the strategic direction of their sector(s) and can provide useful input for regulatory responses to changes. Therefore, in developing strategic directions for the approval path it is important to receive input from industry. Measuring and reporting the approval path's performance and benchmarking New Zealand performance in the approval path against other jurisdictions where relevant and possible will also be needed.

3.5.2. Risk appetite

The two regulatory systems were designed to manage different risks associated with agricultural and horticultural products. It is understandable that different parties have different views on the acceptable level of risk and acceptable level of protection.

For the EPA, the "precautionary approach", which is written into the HSNO Act, means that the regulator has discretion but needs to take a cautious approach in managing adverse effects where there is scientific and technical uncertainty about those

effects. The current EPA strategy says that the EPA's position on the "precautionary approach is *"If we're unsure, we pause and say "no" for now."* (Environmental Protection Authority, 2023).

> For applicants and industry, they perceive the application of the "precautionary approach" as *"overtly risk averse"* (E86) "detrimentally precautionary" (E94) and that the regulator *"underestimated the economic benefits and overestimated the environment and human health risks"* (E79) when applying this approach.

Therefore, some submitters suggested removing the *"precautionary approach"* from the legislation, while others asked for a more flexible interpretation from the regulator or a reconsideration of the EPA stand for the approach.

We note the "precautionary approach" was intended to ensure effective management of risks and not place unreasonable regulatory burden that could harm the economic sustainability (House of Representatives, 1996). The Hazardous Substances and New Organisms (Methodology) Order 1998 was developed to inform the interpretation of the precautionary approach (House of Representatives, 1996). However, the Methodology Order has not been substantially reviewed since 1998.

Some submitters also viewed ACVM as being risk averse in certain cases, for example, the requirements of data for vaccines, and the management of using hemp seed as feed for pets or non-export production animals, and other low-risk products or low-risk applications. We note, it is the legislative expectation (section 76 of the ACVM Act)[52] that risk management is appropriate and poses the least cost. The fact that the ACVM Act was designed to manage risks relevant to other acts and the need to comply with international standards and best practice with trade implications also leads to cautious approaches at times.

Among submitters, there were different views on risk appetite, too. Exporters and environmental stakeholders were supportive of a cautious approach to protect health, the environment and trade interests. It was also noted that New Zealand policy settings require protection to taonga species and Māori rights and interests which may require careful approaches. Differing views on risk appetite are an inherent nature of regulatory systems managing risks – tension between different parties is to be expected. However, there is a risk that over time regulators can become risk averse in response to adverse events, legal challenges, or as their own strategic direction changes. As the Review examines the approval path from outside, with limited time and no technical expertise, it

[52] Section 76 includes that the Minister should recommend a registration exemption if "the likely cost of assessing and registering an agricultural compound as a trade name product is greater than the likely risks from the use of that agricultural compound without registration".

was not possible to ascertain whether this has happened.

The different views on risk and ongoing tension highlight the complexity of risk management and the need for ensuring risk appetites remain appropriate in light of a changing environment. When there are significant concerns about regulators' risk appetite, not for specific applications but as a strategy or an approach to a group of products or a type of applications, it suggests the need for a discussion.

The EPA's obligation under section 7 of the HSNO Act to consider the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects has been the subject of judicial scrutiny and comment (the High Court of New Zealand, 2001, the High Court of New Zealand, 2010, and the Environment Court, 2021). Any discussion on risk appetite should take into account this judicial guidance and how section 7 should be applied on a case-by-case basis.

3.5.3. Prioritisation of resources

Prioritisation of assessments against reassessments

With the queues in mind, stakeholders and submitters raised questions around how regulators prioritise the processing of applications. There was a perception from applicants and end users that the EPA's reassessments of old products are unreasonably prioritised over assessments of new products. Other submitters (from environmental and public health perspectives) felt more reassessments were needed to remove old and harmful chemicals. The EPA advised that they are not prioritising reassessments over assessments of new substances because there are two different teams working on these functions.[53]

Industry asked for transparency around how resources are prioritised across different functions, such as product approvals, reassessments and trial approvals. They believed the EPA's strategic shift from a focus on processing applications and related work, to reassessments, compliance, monitoring and enforcement during the period from 2019 to 2023 (Environmental Protection Authority, 2019) has been one of the key drivers of the queue.

We note that there was a strategic shift in 2019, leading to more investment in reassessments, compliance, monitoring, and enforcement and that the EPA strategy was relevant to various functions, including applications under different legislation for which the EPA is responsible.

The EPA's role is broader than approving new substances, and good regulatory practice requires it to perform all its

[53] Prior to 2020, there was one team working on both assessments and reassessments. In 2020, the EPA separated this into two teams when it received additional funding specifically for reassessments. Since then, the resource in reassessments has been constant and comparable to assessments. Resource in assessments of new applications has recently increased from October 2023 thanks to additional budget appropriation.

functions well. This is consistent with the requirements under the HSNO Act and the expectations set by the Ministers at the time.

We also consider assessment of new products is important to enable access to some new, innovative products, given the availability of these products can indirectly incentivise end-users to phase out the use of old, potentially more harmful chemicals without regulatory intervention. We consider the current distribution of resource between assessments and reassessments within the EPA (with a recent increase in assessments) is reasonable, noting that part of reassessment work is to respond to industry needs (industry-initiated reassessments). In addition, we note that the EPA only undertakes one or two major reassessments (for broader scope of substances than agricultural and horticultural products) every 18 months (Martin Jenkins, 2022).[54] Data on the EPA's website shows that in the period from 2016 to 2023 the EPA undertook eight CE-initiated reassessments compared to 34 Category C (complex applications) decisions.[55] On balance, we consider reassessments are not being prioritised over assessments.

That said, with the EPA's strategic focus on environmental protection, which is required by the HSNO Act and reflected in the current strategic intention (Environmental Protection Authority, 2022), what this means for supporting agricultural industry and New Zealand's economy remains a strategic question to be addressed. We note enabling economic growth is one of the priorities in the environment sector and improving hazardous substances processing times is now a Ministerial expectation (Simmonds, 2024).

We understand that the EPA decided the strategic shift in 2019 because it felt previous investment in customer-centric approach had improved customer experiences and achieved operational efficiencies. With feedback from this Review, the EPA may want to revisit this assessment and continue to improve its customer services.

Some stakeholders asked for a cost benefit analysis when undertaking prioritisation. A cost benefit analysis requires evidence to be provided by applicants, increasing regulatory burden, and adds complexity to the assessment, which can delay process and increase demands on constrained resources. Therefore, this should be considered in light of the HSNO Act's principles and matters relevant to its purpose as well as the purpose of the ACVM Act and the spirit of section 76 of the ACVM Act (regulating in the most cost-effective way).

[54] Completed reassessments and group standard amendments | EPA

[55] Total number of Category C assessment decisions in 2016 (9), 2017 (5), 2018 (3), 2019 (2), 2020 (7), 2021 (1), 2022 (6) and 2023 (1) = 34. Total number of EPA-initiated reassessments decided in 2016 (2), 2017 (1), 2018 (0), 2019 (1), 2020 (2), 2021 (1), 2022 (1) and 2023 (0) = 8. Total number of ALL reassessment decisions from 2016 to 2023 is 22. Total number of assessment decisions for all Category A, B and C from 2016 to 2023 is 253. These include other substances that are not agricultural and horticultural products. More detail on the number of assessment decisions can be found in Appendix C of the Sapere report (Loan et al., 2023).

Transparency of the prioritisation of reassessment of different substances

Reassessments are an integral part of all chemical regulatory systems. Given approvals under the HSNO Act do not expire and are not required to be periodically re-approved as in other jurisdictions, it is critical to the effectiveness of the system and risk management that reassessments occur and are resourced sufficiently.

The EPA has recently been required to publish its three-year CE-initiated chemical reassessment plan following the 2022 HSNO amendments, but prior to this they maintained a list of 'priority substances' for reassessments. The sector asked why reassessment of substances not on the priority chemical list have in some cases been prioritised over those having high ranking priority. This causes frustration for the sector, especially when the reassessment can remove an important substance from use or significantly limit its use without effective replacements available on the market. One example is the reassessment of hydrogen cyanamide, which was not in the EPA priority chemical list.[56] The EPA explained that the decision to reassess this substance was based on new information from the EFSA[57] (now one of the EPA's recognised regulators) and after grounds for reassessment were established following an application from a member of the public. Industry argued that the EFSA paper was available from 2010 and based on data not applicable to the New Zealand context. Industry asked for more robust assessment of grounds for reassessment.

We note that the EPA was still required to establish grounds for reassessment of substances in their priority list at the time the reassessment of hydrogen cyanamide was initiated. The 2022 HSNO amendments added this list to the grounds for assessment and required the EPA to publish its reassessment work plan to increase transparency. This may have meant that at that time the EPA was not ready to initiate a reassessment of a priority substance but could start the reassessment of hydrogen cyanamide because the grounds had been established. We are not able to comment on the decision of the grounds or obtain any further information on the EPA's decision to reassess hydrogen cyanamide before other priority substances.

We expect transparency of the reassessment work plan will be provided after the 2022 HSNO amendments and that when a reassessment is undertaken in an order that is different from the plan, the EPA will provide transparency around its decision.

Prioritisation of assessments of new substances

Prioritisation of assessments of new substances may warrant discussion with industry to ensure limited resources are used in the most impactful manner. Currently, regulators are taking a first

[56] https://www.epa.govt.nz/assets/RecordsAPI/OIA-response-22-July-2022-HiCane-Reassessment.pdf
[57] APP201378 Decision

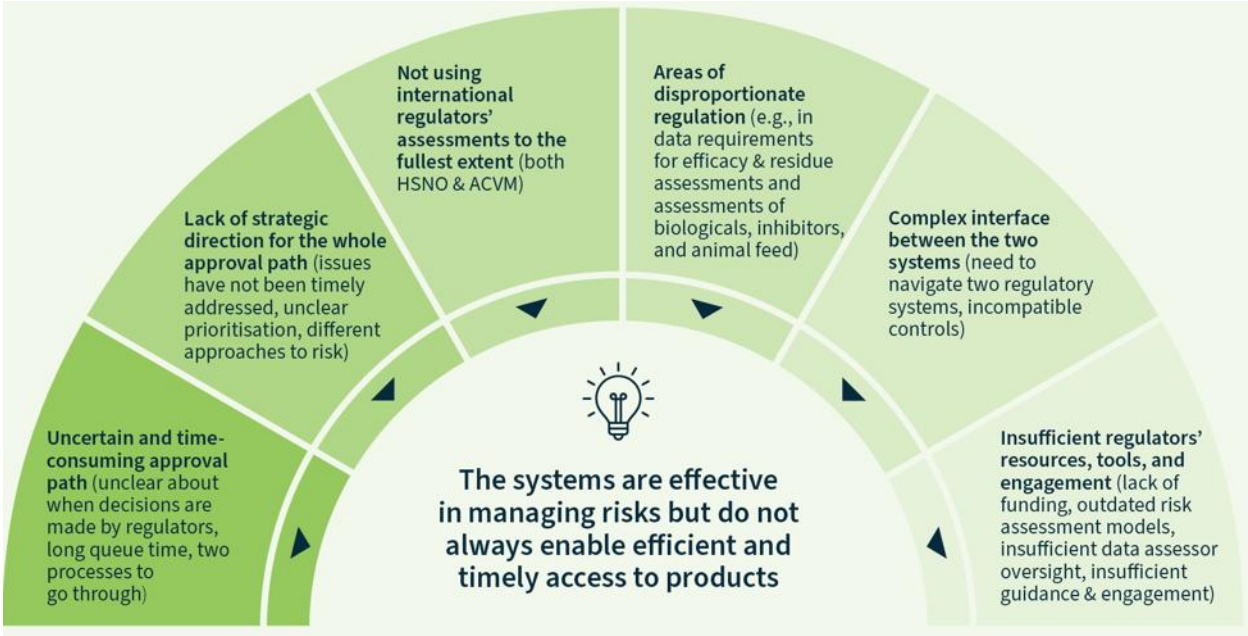
come, first served approach, which has the benefit of being equal and straightforward. We consider there are opportunities for regulators to consider priority for impactful products, given the existing EPA queue. We discuss this in Chapter 5.

The EPA, industry and the sector have started discussion on prioritisation to address the current backlog, but this work was temporarily paused pending the outcomes of this Review. There were also some challenges in determining priority due to the inherent difficulties in trying to prioritise across multiple sectors and workstreams. The EPA noted that, within the primary industry sector, stakeholders did not reach consensus on which substances should be prioritised. We encourage the EPA, the sector and industry to continue this discussion, but also highlight the need for an appropriate forum for these discussions. Prioritisation discussions can shed light on *"what are the must haves and the nice to haves"* (E86) in responding to emerging issues, ensuring industry is empowered with the most effective tools and supporting the move away from using old, more harmful chemicals.

Overall, our view is that a fragmented approval path for agricultural and horticultural products across the two regulatory systems needs appropriate leadership and governance settings as well as strategic directions to guide the coordination of the two systems and drive the responsiveness and adaptation of regulation. This is to achieve the balance of risk management, enabling commercial and innovative opportunities for growth and minimising unintentional consequences of regulation.

Figure 6 summarises the Review's findings on issues of the approval path discussed in this chapter.

Figure 6: Issues of the approval path for agricultural and horticultural products



3.6. Summary

We consider that the systems are effective in managing risks as there is no evidence to indicate regulators are overlooking risks during assessment processes.

However, due to the lack of timely access to new products and other issues discussed in this chapter, we consider the systems have not achieved the balance between enabling access to new, innovative agricultural and horticultural products and managing risks.

In chapter 5, we will recommend changes to address the issues outlined in this chapter.

In this report we have prioritised the most commonly raised issues and those considered most urgent by stakeholders and submitters, particularly where they relate to access to new products.

We are publishing a Summary of Engagement on the Ministry for Regulation's website alongside this report.

Chapter 4: Economic Analysis

This chapter discusses our economic analysis, including key issues such as the role of government and costs and benefits of regulation. Though it takes a first principles approach, many of its conclusions are consistent with the key findings from the Review detailed in Chapter 3 and summarised in Chapter 5. It also provides the outputs of the independent economic modelling commissioned by the Review.

4.1 The agricultural and horticultural products industry is facing challenges and opportunities

From an economic perspective, a key challenge for the agricultural and horticultural products industry is providing suitable access to products, while ensuring the risks of products are managed effectively. Establishing the size of the competitive disadvantage referred to in Chapter 2 is difficult, especially as the ultimate decision to supply products into New Zealand is a commercial one, at the discretion of multinational companies who consider a range of factors. The cost pressures faced by global manufacturers could further direct their investment and product supply toward major markets. This could exacerbate New Zealand's competitive disadvantage.

It is similarly difficult to estimate the impacts of changes in consumer preferences and policies such as the EU's Green Deal[58] and the phasing-out of older chemistry. However, it is certain that consumer choices reflecting their value expectation for sustainability and climate change impacts often go beyond evidence-based regulation.

These global changes are unlikely to improve access by New Zealand users to desired products. While some agricultural and horticultural sectors may be able to find alternative solutions, others may not, particularly the sectors too small to attract investment. Either way, the competitive disadvantage faced by New Zealand makes it crucial that the regulatory system be effective and efficient.

4.1.1. Regulatory management of product risks is part of global risk management ecosystem

While the role for market forces within a broader risk management ecosystem is increasing, so too is the importance of regulation. It is essential that regulators take a forward-looking view to ensure the system they administer accounts for key changes in the market environment. NZFS previously noted:

> *There has been changes in the global political and economic context affecting supply chains, exporters' access to offshore markets and a changed economic environment for New Zealand. … We must continue to monitor for any possible effects from both supply chain and food security pressures on food safety and*

[58] European Commission.

suitability (New Zealand Food Safety, 2022).

The current approval path for agricultural and horticultural products already recognises the need to regulate proportionally. For example, the number of residue trials required under ACVM is often less than that in other jurisdictions.[59] An approach to regulation that aims to keep costs to a minimum, is also reflected in the availability of HSNO rapid assessment pathways, group standards, ACVM exemption from registration and self-assessment changes. The HSNO and ACVM systems are also relatively outcomes-based, with many regulatory requirements applied at the administrative level (for example, guidance documents) and not specified in legislation, as they may be in other countries.

As New Zealand's regulatory systems are a part of a continually evolving global risk management ecosystem, it is crucial the systems reflect the changes that are occurring and the challenges this presents for industry. Regulators also need to be abreast of other opportunities and challenges such as advancements in technology and science that may have impacts on risk management.

4.1.2. There are local opportunities for New Zealand

The existence of a competitive disadvantage does not preclude New Zealand from pursuing local opportunities. These include undertaking trial work on new products to support approvals in northern hemisphere nations, reformulating approved active ingredients or capitalising on its experience in areas like wine production and brewing to create centres of excellence for biopesticides.

The ability to attract new products and develop local opportunities will depend on how well New Zealand compares with other markets. Perceived risks around timeliness of gaining approvals can mean a higher required rate of return or the loss of investment opportunities.

4.2 There is an ongoing role for government in managing product risks

4.2.1. Market failures that require government intervention

Economic analysis, consistent with the views of most stakeholders, supports the ongoing regulation of agricultural and horticultural products. The most significant value from the regulatory system comes from the confidence it provides consumers and overseas regulators. This is crucial for continued market access. An overview of the market failure issues for the risks and trade (market access) are shown in Table 7.

It is difficult to be definitive about the extent of market failure for the direct risks associated with agricultural and horticultural products. NZFS provided the Review with examples of reassessments of

[59] For example, the maximum number of residue trials in the USA for apples is 16. In New Zealand it is 6.

several products because of residue issues. It also provided confidential examples of where, following testing, products were recalled or reformulated due to risk-related concerns.

While these examples highlight the need for oversight, the available evidence does not suggest a systemic problem. This could be because the overall regime is effective, with regulatory enforcement providing a level of influence that cannot be achieved through self-regulation. It is also likely that improvements in the amount of available information, including on the science of food safety, and greater scrutiny of business activity, have lessened, in recent years, the prevalence of information asymmetries and externalities.

Table 7: Market failure overview

	Market Failures	Market failure considerations
Human health (usage)	Information asymmetries Externalities	• Large manufacturers have a strong incentive to supply safe products. There are significant financial consequences of not doing so, as an incident would impact their global reputation. • There may be a risk with suppliers who may not be invested long-term in the industry. • End-users should be more informed about risks, have incentives to manage them and value their social license for conducting agricultural and horticultural activity. However, there are still opportunities for "rogue" users to do the wrong thing. • Some risks are reduced by the impact of industry-led initiatives and market forces, based on consumer preferences and greater access to information about food safety.
Human health (food safety)		
Animal health		
Plant health		
Environment		• There is a great scope for detrimental impacts on the environment as they may take time to manifest and may be harder to detect. • Reliance on risk assessment by overseas regulators is limited by different local conditions.
Trade		• The economic and social flow-on effects of a product causing a food safety incident are very high for New Zealand, given its reliance on trade. • While there is always some risk with farmers and growers using the product incorrectly, either knowingly or unknowingly, greater available information has increased awareness of the potential for such damage.

Trade (market access)	Club good[60]	• While the market is increasingly involved in risk management, there will always be a role for government on trade negotiations and conventions. Government-to-government assurances on trade need to be backed by an effective regulatory system. • Coordination and agreement on MRLs benefits New Zealand exporters.
Animal welfare	Information asymmetries	• There are market failure issues with animal welfare, anti-microbial resistance and agricultural security. • While the ACVM system can assist in managing these market failures through its approval path, it is not the most significant lever available to government.
Anti-microbial Resistance	Externalities	
Agricultural Security		

In terms of the product manufacturer and importer, there is a strong incentive on suppliers to protect their reputation by conducting appropriate risk assessment and providing end-users with the required information. In terms of end-users, digital connectivity and industry-led programmes have increased farmers and growers' awareness of potential product risks. Some of New Zealand's primary production export sectors, such as dairy, meat and wine, are more mature than others and have a stronger incentive to manage sector-wide risks, including maintaining their export reputation.

The strongest case for market failure relates to the environment. There is a greater scope for information asymmetries and externalities, given harm to the environment can take time (years to generations) to manifest and may be more difficult to detect and pinpoint than food residues, for example. The need to understand local conditions and how they may interact with products already approved overseas is also important.

4.2.2. The role of government in assessing and verifying efficacy is sometimes questioned

One area of the regulatory system where the role of government is sometimes questioned, is the requirement to provide efficacy information on products. This issue is multi-faceted. While the EPA does not request efficacy information from applicants,[61] NZFS, to meet the requirements of the ACVM Act, does.

[60] Section 19 of the ACVM Act lists market access as a risk. MPI also considers market access a club good, based on its analysis of excludability and rivalry of output benefits (Ministry for Primary Industries, 2018).
[61] The HSNO Act requires information about the benefits of substances, which may or may not include high-level efficacy information provided by applicants.

Efficacy information for end users

Efficacy is obviously important to end-users. Like most other goods and services sold in the economy, the major influence on whether a product does what it says it will do is market forces. Farmers and growers are unlikely to consistently spend their money on poor-performing products.

To supplement competitive pressures, agricultural and horticultural products are also subject to the Fair Trading Act 1986 and Consumer Guarantee Act 1993.[62] In addition, one of the legislative purposes of the ACVM Act is to "*ensure the provision of sufficient consumer information about agricultural compounds*" (House of Representatives, 1997b). This has been interpreted to include efficacy claims.

Efficacy information's role in risk management

NZFS requires efficacy data be provided to assist it to manage direct risks, such as human health (food safety). Knowing the efficacy of the product can help inform the regulator about how it will be used and ensure that the label rate they are considering will be effective. A product that is not effective can lead to over-use, which can then impact residue levels or animal welfare.[63]

In addition to direct risks, efficacy information is used to assist in the management of risks relating to animal welfare, resistance issues and agricultural security. If an insecticide or pesticide does not perform as expected, it can have significant impacts such as resulting in a pest spreading and becoming entrenched.

ACVM bundled approach

In principle, the purpose of the ACVM and HSNO regulatory systems is to manage the risks inherent to the product or substance. The decision by NZFS to require efficacy information, unlike the EPA, is due to the ACVM Act having multiple purposes and a direct relationship with other acts (for example, Biosecurity Act 1993).

> The risk with bundling various risks and issues together is that NZFS may not always adopt a case-by-case approach to the requirements it places on applicants. As with risk management in general, efficacy requirements should be proportional. If the direct risks do not warrant efficacy data, then it should not be required, unless there is a strong basis for it on other grounds (for example, agricultural security).

This bundled approach can achieve cost efficiencies for government. Once required for direct risk assessment purposes, there is minimal additional cost to the applicant of using efficacy information to support other legislative purposes. However, it should be noted that while this information is of value, the ACVM approval process is not the primary means of achieving other policy outcomes. In the case of anti-microbial resistance, for example, the government has a much wider programme in place.

[62] Section 12A of the Fair Trading Act prohibits unsubstantiated representations, with unsubstantiated being defined as when a "person making the representation does not, when the representation is made, have reasonable grounds for the representation, irrespective of whether the representation is false or misleading".
[63] It is also possible for a product to be "too efficacious", causing animal and plant health issues.

4.2.3. The role of government in supporting market access is important

In addition to market failures relating to various risks, the ACVM Act recognises the importance of the approval pathway in terms of market access. Market access is a club good, rather than a risk. There is a justified role for government to create this "good" by negotiating trade agreements and maintaining relationships with other countries. New Zealand exporters can then take advantage of the benefits, provided they meet certain requirements.

4.2.4. Industry has a complementary role in supporting risk management

The role of industry does not compete with or necessarily overlap with risk management undertaken by government. For example, there is a clear need for independent, science-based assessments of product risks, and for government-to-government assurances on safety. Greater collaboration and better alignment of the regulatory system with industry-led efforts can reduce the costs of approvals and allow resources to be directed to other priorities, while still maintaining the confidence of other regulators and markets.

Complementary roles may in the future be able to be extended to enable greater industry and government collaboration. This might include leadership across agencies, developing a strategic direction for the approval path with input from industry, or increased use of self-assessment (for example, more HSNO group standards).

If any future changes to governance or leadership arrangements were to be proposed they would need to ensure they did not compromise the independence of regulatory decisions. This would include effective management of perceived conflicts of interest.

4.2.5. There is potential for a strategic response to reflect New Zealand's competitive disadvantage

It is important that regulators and the regulatory system be adaptive. Given the competitive disadvantage and current trends, New Zealand is not favoured as the first jurisdiction to approve a major new active ingredient. This outlook may warrant a strategic response that allows New Zealand's regulatory system to be more bespoke, leveraging the decisions of better-resourced overseas systems and making any needed adjustments for local conditions. This might include, for example, directly incorporating the risk assessments made by other regulators. As noted in the following chapter, the Review recommends greater use of international regulators' assessments.

4.3 It is important to clearly understand the costs and benefits of regulation

As discussed in Chapter 2, there is an important distinction between the costs and benefits of the product, and the costs and benefits of regulation. While the

product is obviously important and generates the need for risk management, it is the decision to intervene, and its costs and benefits, that is most relevant to the Review. It is vital the regulators remain aware of this principle, which is captured well in section 19 of the ACVM Act which states that, amongst other things, regulatory decisions must consider "the likely consequences of the public not having access, or having restricted access, to" the product.

4.3.1. HSNO approach

The approach to costs and benefits under HSNO is relatively straight-forward and consistent with its primary purpose of managing risk. For example, under section 96C(2)(d) of the HSNO Act, the "*EPA must be satisfied that the benefits associated with a reduction of environmental and health risks outweigh the economic costs associated with complying with the group standard.*"[64] Based on the illustrative figures used in Appendix 1, this reflects the principle that 'the reduction in risk due to regulation' should be greater than 'the costs created by regulation'.

4.3.2. ACVM approach

The AVCM approach to costs and benefits is more complicated, given the various risks the approval path manages and its support for the club good of market access. Sections 19, 20 and 21 of the ACVM Act refer to "*risks and benefits*". As noted in Chapter 2, however, the key trade-off for a regulator should be the balance between risk reduction (the benefits of regulation) and costs of regulation. A risk-cost framing, rather than risk-benefit,[65] would encourage the regulator to constantly ask what costs will be incurred if it has to restrict access to the product.

4.3.3. Balancing costs and benefits

Each regulator is already required to weigh up all the relevant costs and benefits. The EPA must consider the economic and related benefits and costs of using a particular hazardous substance or new organism. In the case of ACVM, the bundling of different purposes, as with efficacy, has the potential to complicate the process.

The fundamental benefit of the ACVM regulatory system is reduced risk, not access to the product. On this basis, the focus for NZFS should always be to ensure the costs associated with this reduction in risk are achieved at least-cost. This can come into tension with the role played by the ACVM approval path for other purposes.

[64] Note that section 96C(2)(d) of HSNO relates to a manufactured article, a waste product, or a manufacturing by-product. Though not directly applicable to agricultural and horticultural products, it is a good example of the relevant principle in legislation.

[65] Consistent with the risks and benefits terminology used in the Act, the select committee stated that "there may be instances where risks are not acceptable and that a risk-benefit trade-off may be necessary" (Transport and Environment Committee, 1997).

In the case of market access, for example, trade facilitation needs can place certain expectations on the design and operation of the regulatory system. While this may be appropriate, it is important any requirements relating to market access or efficacy be weighed against any cost imposition on applicants and the flow-on impact on end-users. If not, efforts to assist our exports could end up undermining them.

4.4 Independent economic modelling

To provide quantitative context for some of the key issues for the Review, and in line with the Review's terms of reference to consider the costs and benefits of regulation more broadly, we commissioned an independent economic consultant, Sense Partners, to model three scenarios. Sense Partners used high-level models to estimate the benefits of improving the assessment process for agricultural and horticultural products.

Scenario 1 considered the effects of reducing regulatory approval times by half, for all products and sectors. Sense Partners used a model to estimate the market value of new products and then made assumptions about gaining earlier access to the products.

It estimated that reducing the current approval times for new products by half is estimated to generate present value benefits of $272 million over 20 years to product users.

Scenario 2 considered the effects of more stringent regulations leading to New Zealand fruit and vegetable exporters having reduced access to EU markets due to an inability to access newer and "softer" products. It modelled the loss of access to new products as an effective increase in trade costs. It then applied a probability rating to arrive at the "value at risk".

The present value cost of not being able to respond to EU regulatory changes for horticultural products was estimated at $250 million over 20 years.

Scenario 3 considered the effects of a delay in the development of a new methane inhibitor. The consultant developed a model to estimate the impacts of the delay, assumed the uptake of the inhibitor also required the introduction of a climate change incentive, such as agricultural emissions pricing or a direct subsidy.

The benefits of reducing the regulatory delay of a new, hypothetical methane inhibitor range from a net present value of $43 million to $183 million over 20 years, depending on the level of market penetration and policy incentive used to encourage adoption.

5.1 Summary

This economic analysis highlights the need to understand the market characteristics, global trends and evolving risk management ecosystem for regulating agricultural and horticultural products.

It also clarifies the distinction between benefits of the product and the costs of regulation.

This will help guide risk management in an appropriate manner to reduce any unnecessary burden on regulated parties and not exacerbate New Zealand's competitive disadvantage.

Chapter 5: Findings, Recommendations and Next Steps

5.1 Introduction

In this chapter we summarise Review's findings on the issues (and underlying causes of the issues) with the approval path in Chapter 3 and the economic analysis, which guide our consideration of a range of options and the development of recommendations to improve the approval path for agricultural and horticultural products.

We gathered potential options from a range of sources and developed an assessment framework to consider potential options. We:

a. assessed the extent to which the options achieve the objective of the Review;
b. evaluated how the options perform against a set of pre-determined criteria; and
c. analysed the impacts on various stakeholders.

We tested the options and recommendations during our engagement process. We note that detailed regulatory impact assessment, and consideration of wider policy implications will be needed as part of implementation, especially for legislative changes, cost recovery arrangements, and investment in regulatory infrastructure such as risk assessment models. This analysis will be undertaken when agencies develop specific proposals to give effect to Government decisions after considering our final recommendations.

5.2 Findings about the issues with the approval path and their underlying causes

We report analysis of issues and underlying causes of the approval path of products in Chapter 3 and economic analysis in Chapter 4. Our findings are summarised as below.

- **Finding 1:** Overall, the regulatory systems are effective in managing risks, however, the approval path does not always enable efficient and timely access to new products and new uses of products.
- **Finding 2:** The current processes can be time consuming and uncertain. Industry and stakeholders believe the length and uncertainty of the approval path have caused significant impacts on industry and may exacerbate New Zealand's competitive disadvantage.
- **Finding 3:** The interface between the ACVM and HSNO regulatory systems introduce complexity for applicants and end users of products. This includes the need to understand the alignment of any controls on products imposed by each regulator, how to enable off-label uses to support growers of minor crops, how to ensure product data protection (where relevant), and other issues.
- **Finding 4:** There are efficiency concerns relevant to the approval path where international regulators' information has not been used to the

fullest extent and "light-touch' pathways have not been fully used to ensure the proportionality of regulation.

- **Finding 5:** There are concerns relevant to regulator's resources, tools, and engagement. The EPA's risk assessment models are outdated and no longer fit for purpose. The ACVM data assessor framework needs to be strengthened. Working with limited resources, regulatory agencies have put significant effort into engaging and communicating with regulated parties but there is still room for improvements, both at operational and strategic levels.
- **Finding 6:** There is no strategic approach for the approval path across the two regulatory systems. The approval path needs appropriate forums to discuss strategic outlook, undertake horizon scanning, and discuss priorities and approaches to managing risks with input from different perspectives.
- **Finding 7:** The regulation of risks associated with agricultural and horticultural products should take into account New Zealand's competitive disadvantage, relevant trends and an evolving risk management ecosystem. If New Zealand's systems do not continue to be pragmatic and proportional, they may fail to support the primary industry sector.

5.3 Recommendations to address the findings of the Review

We have developed 16 recommendations to respond to the findings as below. We also note an opportunity outside of the regulatory systems and work underway by agencies, that support improved outcomes.

5.3.1. Recommendations to establish strategic direction for the approval path

Recommendation 1: Recommend the formation of a Sector Leaders Forum

This recommendation relates to findings primarily associated with complex interface issues, regulator engagement and communication, strategic direction and other issues.

Membership of the Sector Leaders Forum should include senior representatives of the regulators, policy agencies, and key stakeholder and sector groups with an interest in agricultural and horticultural products. At times, this may need to include representatives of related regulatory systems, such as biosecurity.

The purpose of the Sector Leaders Forum would be for:

a. both regulators to provide transparency over the performance of both regulatory systems and of the approval path as a whole;
b. sector leaders to raise issues and feedback on the approval path with leaders from regulators and policy agencies, and discuss potential solutions;
c. discussing significant initiatives underway or planned across the

regulatory systems or within the sectors; and

d. undertaking horizon scanning for future challenges the approval path or sectors will face.

At the end of each Forum, participants should draft and agree a summary of the discussion, outcomes and actions from the meeting. Officials should provide this summary (along with the latest performance reporting, which we will discuss in recommendations 3 and 13) in a joint briefing to the Minister for Food Safety and Minister for the Environment. Developing an agreed summary of the meeting is consistent with the approach that many international forums take, and ensures that all parties are clear on the discussion, and any concerns are promptly raised to Ministers for transparency and accountability purposes. Participants drafting a shared summary ensures that outcomes and actions are mutually agreed and reflect the views of the participants.

The summary from the Sector Leaders Forum would provide shared visibility for Ministers of the performance of the approval path, implementation of this Review's recommendations and any upcoming challenges. This would also enable Ministers to identify areas where further joint advice would be of value, or matters Ministers may wish to include in a future ministerial letter of expectations or directions. Responsible Ministers play a key role in utilising the levers available to them to ensure actions are taken to respond to issues and opportunities raised.

In the immediate term, the forum should also discuss the implementation plan for this Review's recommendations, develop the common grounds, objectives and purpose of the Sector Leaders Forum, and build and strengthen the initial trust and relationship between the sector and regulators. We recommend that for the first two years, the forum meets quarterly for this reason. Longer term, an annual forum may be more appropriate but should be discussed with and agreed by the forum members.

Responsible agencies would need to determine who is best placed to administrate and facilitate such a group. There would likely be value in bringing in independent expertise, such as risk management, for relevant discussions.

The design of the group should be specific to the regulatory systems for the approval of agricultural and horticultural products. There are other current or former groups and bodies[66] which may provide some lessons learnt, however their design should not be directly transferred given the differences in purposes and contexts. The Chair of the Forum could be appointed by Ministers, although we are not recommending this due to the added costs and complexity this would add without clear additional benefits.

[66] For example, the Food and Fibre Partnership Group, Biosecurity Ministerial Advisory Committee, Food Safety Assurance Advisory Council, and Dairy Products Safety Advisory Council.

Assessment of recommendation's impacts and implementation

This forum would enable improved engagement at the leadership levels between industry and regulators, provide shared Ministerial visibility over the approval path and upcoming challenges, and ensure coordinated understanding of the challenges the approval path faces, and the roles that the sector and government can play. It would enable transparent accountability over the implementation of this Review's recommendations. The terms of Reference for the forum should be developed, where appropriate.

Such a forum would likely require resources to facilitate and service. The benefits of a forum are hard to quantify but this forum would provide an opportunity to ensure the challenges facing the system are jointly understood, and that opportunities to improve the efficiency, effectiveness, proportionality and transparency are identified and actioned promptly and appropriately.

Ministers will need to receive advice on the implications of resourcing this forum within existing baselines, and any trade-offs that would need to be made. Reducing resourcing available to process applications would be a worse outcome than the *status quo*. There are likely design features that could reduce the resourcing and process burden.

Overall, we estimate the impact of this recommendation to be medium to high. This and other recommendations would be a key mechanism in ensuring the approval path remains fit for purpose for the future.

This recommendation would have costs in the form of the time and resources required to facilitate the forum. These can be minimised through the design and terms of reference of the forum, to be determined in implementation.

Recommendation 2: Recommend that the Minister for the Environment and Minister for Food Safety ensure prompt implementation of this Review's recommendations and are required to consider issues raised by the Sector Leaders Forum

This recommendation relates to all findings.

New Zealand constitutional convention is that Ministers are accountable to the House of Representatives (and therefore the New Zealand public) for setting policy priorities and providing oversight, while Chief Executives and Crown entity boards are responsible for ensuring their organisations operate efficiently and effectively.[67] We recommend that Ministers closely monitor the implementation of these recommendations, particularly consider issues raised by the Sector Leaders Forum, and take action as appropriate. While we consider it is inappropriate for the Sector Leaders Forum to have decision-making powers, the feedback of the forum may inform where Ministerial action or additional advice may be required. Some of the actions available to Ministers as decision-

[67] https://www.dpmc.govt.nz/sites/default/files/2023-06/cabinet-manual-2023-v2.pdf and paras 3.31 and 3.26

makers of the regulatory systems are outlined below.

Relationship between the Minister for the Environment and the EPA

As a Crown entity, the EPA Board is accountable to the Minister for the Environment.[68] While the EPA, as with other Crown agents, must give effect to government policy when directed, section 17 of the HSNO Act specifies that the responsible Minister may not give direction that relates to functions or powers of the EPA under the HSNO Act – this includes hazardous substances applications and reassessments. Nevertheless, the Minister for the Environment has levers to ensure accountability and to fulfil their role of monitoring the EPA's performance.[69] Formal actions available to the Minister for the Environment include:

- providing letters of expectations outlining their expectations for the EPA's performance and priorities;
- providing feedback or direction as to the content of the Statement of Intent, for which the EPA is due to produce an update in 2025;[70]
- providing feedback or direction as to the content of the statements of performance expectations;[71]
- ensuring the EPA Board has the appropriate knowledge, skills and experience to assist the EPA to perform well and deliver these recommendations;[72]
- engaging regularly and directly with the EPA Chair / Board to set expectations and provide feedback on performance;[73]
- requesting information and updates for performance review, such as in the quarterly performance reports;[74] and
- providing direction to the Ministry for the Environment on monitoring of the EPA, and request advice or analysis as required on any matters.

Relationship between the Minister for Food Safety and NZFS

The relationship between the Minister for Food Safety and MPI, including NZFS, is different. As a public service department, MPI (including NZFS) is directly responsible to the Minister for Food Safety for matters within the Food Safety portfolio and must implement the decisions of the Government. While such direction can be informal, it can also be provided by way of a general policy direction under section 38

[68] Section 26 (2) of the Crown Entities Act 2004.
[69] Section 27(1)(f) of the Crown Entities Act 2004.
[70] Section 145 and section 147 of the Crown Entities Act 2004.
[71] Sections 149B, 149H, 149E, 149I and 149J of the Crown Entities Act 2004. Crown Entities are required to act in a manner consistent with their statement of intent and statement of performance expectations.
[72] Section 29 of the Crown Entities Act 2004. We note that the EPA Board has recently had several new members, and an Acting Chair is currently in place.
[73] https://www.publicservice.govt.nz/assets/DirectoryFile/Guide-for-Ministers-Statutory-Crown-Entities-performance-levers.pdf
[74] Section 27(1)(e) of the Crown Entities Act 2004.

of the ACVM Act.[75] The Minister may also specify priorities and the performance expectations within key accountability documents, including:

- one-year performance information, to be found for example in supporting information to the Estimates of Appropriations;
- medium-term performance information, found for example in information on strategic intentions as required by section 40 of the Public Finance Act 1989;
- plans providing a medium and long-term perspective on agencies in the context of their longer-term vision, and as appropriate, for the nature of their operations, such as investment or workforce plans; and
- short-term plans and reporting as agreed between the chief executive and the relevant portfolio Minister for each Vote the agency administers when more detail is needed than that included in the supporting information to the Estimates.[76]

Other Ministerial interventions

In addition to the processes outlined above, Ministerial and Select Committee processes for setting budgets and reviewing the performance of agencies and Crown entities provide mechanisms for accountability and transparency of performance. Ministers can also directly seek explanation on any perceived performance issues. Ministers may also ask for advice from the Ministry for Regulation (via the Minister for Regulation) if they consider independent expertise is required.

Use of Ministerial interventions to ensure the implementation of this Review's recommendations and respond to issues raised by the Sector Leaders Forum

The full range of levers available to Ministers need to be used to ensure prompt implementation of this Review's recommendations and respond to issues raised by the Sector Leaders Forum. For example, Ministers can use the above levers to request targets to reduce the queues (recommendation 3). Ministers can also use them to issue direction,[77] set expectations or convey feedback in response to issues raised in Sector Leaders Forum meetings. Ministers can request information on performance against targets, and have regular conversations with MPI and MfE Chief Executives and the EPA Board (Chair) to convey the priority of implementing these recommendations.

[75] In the exercise and performance of his or her functions, powers, and duties under this Act, the Director-General must have regard to those policies of government that are applicable to agricultural compounds and must comply with any general directions relating to that policy given to the Director-General from time to time by notice in writing signed by the Minister.

[76] https://www.dpmc.govt.nz/sites/default/files/2023-06/cabinet-manual-2023-v2.pdf

[77] Sections 103, 107 and 114 of the Crown Entities Act 2004. Note section 115 requires a Minister to consult with the entity prior to giving a direction, and to publish in the Gazette and present a copy to the House of Representatives.

Assessment of recommendation's impacts and implementation

The impact of this recommendation is high, as it would ensure the impacts of other recommendations are realised.

For example, in response to the 2024/25 Letter of Expectations from the Minister for the Environment (Simmonds, 2024), the EPA made improvements in its performance reporting (including detailed information on HSNO performance in quarterly reports and setting a queue reduction target in its 2024/25 Statement of Performance Expectations).

This can be further improved with input from the Sector Leaders Forum to meet future needs, not only for the HSNO regulatory system but also for the approval path across the two regulatory systems.

The complexity and resource required to implement is low as these are existing powers and functions available to Ministers. The complexity of implementing a direction or expectation from Ministers depends on the nature of the direction/expectation.

5.3.2. Recommendations to reduce application queues

Recommendation 3: Recommend that the Minister for the Environment and Minister for Food Safety set expectations for targets to accelerate HSNO and ACVM processes and reduce queues

This recommendation relates to findings associated with New Zealand's competitive disadvantage, enabling timely access to products, approval path's speed and certainty, proportionate regulations, and regulator capacity and resourcing.

As discussed in Chapter 3, a key issue facing the approval path is the large queue of applications awaiting EPA assessments. While the queue has started to decrease, there is a need for further reduction. This is one of the highest priority issues to be addressed. While NZFS's queues are of lesser concern, it is still an area where improvements are needed.

Given the EPA's status as a Crown agent, we recommend that the Minister for the Environment write to the EPA to set out their expectation of targets to accelerate assessments and reduce the queue given the Minister's previous expectations. As part of the Minister for Environment's communication with the EPA in this regard, we recommend a request for the EPA to publicly set out its plans for meeting these targets.

We recommend that the Minister for Food Safety direct the Ministry for Primary Industries and New Zealand Food Safety on targets to accelerate approvals and reduce the ACVM queues, and that a plan for how this should be achieved be published.

Any strategies or plans for the reduction of the queues ultimately developed by agencies, in conjunction with responsible Ministers as appropriate, should be both specific and ambitious. These targets should be included in existing accountability mechanisms, and progress should be reported publicly, including in

the Sector Leaders Forum's meetings. The Ministry for Regulation can provide feedback on any proposed targets or guidance at the Ministers' requests, and Ministers may wish to test newly developed strategies with the Sector Leaders Forum.

Robust and ambitious targets will support attention, resources and accountability to be focused on improving outcomes, and encourage a balanced approach to risk (OECD, 2014).

Many of the Review's recommendations should improve the speed at which agencies can assess applications, which would enable the queues to further reduce. We also recommend the EPA continue identifying applications in the queue that can be addressed through new group standards and the existing rapid assessment pathways to hasten the queue reduction.

Assessment of recommendation's impacts and implementation

This recommendation is for short term intervention but would support improved efficiency and longer-term greater proportionality. Information and progress against any targets should be shared with the Sector Leaders Forum and Ministers, to track progress on accelerating approvals and reducing the queues.

Given the EPA queue is one of the most significant challenges facing the timely approval of agricultural and horticultural products, this recommendation is likely to have a high impact. We note the EPA has already started this as part of their commitment to reduce the queue.

Achieving ambitious targets and preparing the necessary advice to inform such decisions may have resource implications for agencies, which should be identified for Ministers when advice is being given.

The resource implications would depend on the targets set by agencies and any feedback given by Ministers. For the purposes of Figure 7, we have assumed targets would be achievable within current resources.

Given the work agencies have already initiated to reduce the queues, we have assessed the complexity to implement this recommendation as low. However, if targets are not achievable within existing resources, then the complexity and resources required would be higher.

5.3.3. Recommendations to streamline the interface between the ACVM and HSNO systems

Recommendation 4: Recommend that MPI, MfE, NZFS and the EPA make the two regulatory systems easier to navigate

This recommendation relates to findings associated with complex interface issues, regulator engagement and communication, and strategic direction.

A common theme of issues raised during the Review has been the challenge of navigating the two regulatory systems. This issue was considered at the time the HSNO and ACVM Acts were developed in the 1990s. While collaboration and communication may reduce the challenges, differences will remain and were intentional in the design of the approval path. There is an option for significant legislative changes to overhaul the current design, however, we recommend retaining two regulatory systems as explained in Appendix 3.

Both regulators have expressed (to different extents) that they see their regulatory system as operating independently from the other. However, both regulatory systems need to be navigated when bringing a new product or introducing new uses of existing products to the New Zealand market, and there are no process maps or guidance available to clarify the available pathways across both systems.

Given the challenges and issues the Review identified, we recommend agencies increase their collaboration and communication to identify opportunities to improve outcomes. While there are examples of this occurring at the operational level, we consider this needs to be prioritised and include appropriate senior leaders.

Opportunities we have identified, and which should be considered further include:

- combined guidance and process maps on how to obtain approval through both regulators;
- providing guidance on how to obtain product data protection through both regulators, or providing data protection through the EPA directly;
- joint pre-application meetings with both regulators;
- staff members that are a first point of contact providing initial guidance for both regulatory systems;
- sharing industry knowledge and technical expertise relevant to the application;
- sharing information on alignment of controls, impacts of any potential off-label uses and any other interface matters.

Assessment of recommendation's impacts and implementation

This recommendation would mainly improve efficiency and proportionality as it would reduce the regulatory burden associated with navigating the two systems. It also provides some benefits for transparency and certainty.

The impact of this recommendation will depend on the opportunities progressed.

Generally, we consider that improved consistency across the regulatory systems and ease of navigation will have moderate impact.

While only a small percentage of applications are processed by regulators at the same or similar times, those that do are likely to be innovative new products.

The complexity to implement this recommendation depends on the opportunities progressed, but our initial assessment is moderate.

5.3.4. Recommendations to achieve efficiency and proportionate regulation

Recommendation 5: Recommend that agencies increase the use and better design of group standards, rapid assessment pathways, registration exemptions, and self-assessable changes

This recommendation relates to findings associated with New Zealand's competitive disadvantage, enabling timely access to products, approval path's speed and certainty, proportionate regulations, and regulator capacity and resourcing.

MfE/the EPA

An advantage of the current system is the ability for the EPA to create group standards under the HSNO Act, which enables broad approvals for products of a similar type and use.

There are several group standards covering agricultural and horticultural products. Increasing use of these tools by creating additional group standards for eligible products would enable the regulator to use its resources more efficiently by focusing on products that are higher risk and require greater New Zealand specific assessment. We have identified low hazard biopesticides and methane inhibitor feed additives as initial areas where group standards should be developed.

The EPA should consider if group standards can be created, amended or revoked in a more flexible way, or by creating a pathway for substances to be declared 'equivalent' to a group standard. This should be considered by the EPA and MfE in the design of future group standards (to ensure any constraints are appropriately flexible), or in any planned legislative amendment. There may be value in a new rapid pathway under section 28A (2) of the HSNO Act for substances that are of equivalent risk or can be managed in the same way as an existing group standard.

Receiving feedback on the design and process of group standards via the Sector Leaders Forum and other engagement forums can support ensuring they are appropriate for end users, and coordinate with other risk management initiatives.

Another advantage of the HSNO system is that the HSNO Act provides for rapid assessment pathways that enable accelerated processes for certain applications meeting legislative criteria. We support increased use of these pathways to reduce the HSNO queue size and improve access to products where appropriate.

MPI/NZFS

An advantage of the current system is ACVM registration exemptions, which enable products to be imported and manufactured when individual assessment is not required, by applying general controls and conditions via regulations.

Increasing use of registration exemptions for the eligible products would enable the regulator to use its resource more efficiently by focusing on products that are higher risk and require greater New Zealand specific assessment.

Exemption registrations should be made more flexible and agile by moving to a Ministerial notice. Updating the exemption via an order in council or a Ministerial notice would require the same level of risk assessment undertaken by NZFS and certain input from interested parties or the public. However, the order in council process would require more time and resources, including those of Cabinet and Parliamentary Counsel Office. We consider this is not proportionate, given the regulations are for managing low risk products, and needs to be updated frequently. There is also an opportunity to be flexible with the level of engagement required for changes. Targeted engagement with interested parties may be appropriate in some cases, for example, minor amendments to conditions, whereas other changes may justify broader engagement.

There would be value in enabling the MPI's Director General to provide time-limited exemptions to products which are equivalent in risk to exempted products, while robust definitions and categories are developed for inclusion in the regulations/exemption notice. This would be consistent with powers under other MPI legislation.[78] Currently, products of this nature must be individually assessed until the regulations are updated. While changing the design to Ministerial notice would reduce the time between updates, NZFS would still need to take time to develop robust definitions and constraints for the whole category, even if satisfied that a specific product does not require registration. The full assessment for these products could result in resources being directed to unnecessary work, and unnecessary costs on applicants. This can direct resource away from applications that do warrant specific assessment, reducing the overall efficiency of the approval process.

Another advantage of the ACVM system is self-assessable changes, such as

[78] Such as sections 33 and 347 of the Food Act 2014, section 14 of the Animal Product Act 1999, and section 11 of the Wine Act 2003.

manufacturing site changes, which reduce the burden on applicants for low-risk applications. A self-assessable change can be implemented without prior approval from the regulator. The change is then notified at the next variation or renewal.

Self-assessable changes should be maximised to enable proportionality. There may be some limited scope to extend self-assessable changes without affecting the effectiveness of risk management. Many of these are low risk changes, and do not require technical assessment; others can have implications for the risk management of a product.

NZFS has already identified changes to the manufacture/chemistry of a veterinary medicine that can be self-assessed. These are detailed in existing guidance (New Zealand Food Safety, 2024). NZFS works with industry to identify new changes that could be considered self-assessable. Other regulators such as Medsafe also use 'self-assessable' pathways for certain changes to products, as does the APVMA in specific circumstances.

Given that approximately 90% of the applications processed by NZFS are variations to existing approvals, this represents a significant proportion of the regulator's time, and a notable proportion of the regulatory burden on regulated parties. We recommend that MPI and NZFS ensure that self-assessable changes are being used to the fullest extent practicable without compromising the effectiveness of risk management.

Assessment of recommendation's impacts and implementation

This recommendation would improve the efficiency, transparency, certainty, and proportionality of the regulatory system. This may also help remove future applications from the queues, reducing the EPA backlog, although resource could be needed to implement.

Receiving feedback on the design of group standards and changes to registration exemptions via the Sector Leaders Forum and other engagement forums would ensure they are appropriate for end users' practices, and coordinate with other risk management initiatives.

The impact of this recommendation depends on the number of group standards developed/amended, their design, and the scale of changes to exemption regulation and self-assessment. We estimate it to be moderate to high; making the design more flexible would have a high impact long term.

Developing group standards takes time and will have resourcing implications. Updating the existing exemptions is relatively straightforward as MPI has commenced this work. However, changing the design of the registration exemptions (for example, to a Ministerial notice) would require primary legislative change, which can take some time.

The scale of impact from self-assessment changes could be moderate to low, given many self-assessable changes have already been identified. As an extension of an existing operational approach, the complexity to implement should be low.

Recommendation 6: Recommend that MPI and NZFS reduce ACVM efficacy requirements for inhibitors to the minimum required to manage risks

This recommendation relates to findings associated with New Zealand's competitive disadvantage, enabling timely access to products, approval path's speed and certainty, and proportionate regulations.

As discussed in Chapter 3, inhibitors are different from conventional products and incorporating them into an existing regulatory system has posed challenges. As noted in Chapter 4, market failure analysis identified a need to ensure efficacy requirements are proportionate to risks managed by the ACVM and HSNO systems.

We consider there is a need to streamline or reduce requirements of efficacy data for registration of these products, while still effectively managing risks. This may include taking a more qualitative approach to assessing benefits under the ACVM Act. It should also have regard for the ability of the market and other initiatives to provide efficacy information and the impact of other information requirements (for example, environmental reporting).

We note MPI and NZFS are already considering work in this space, which we endorse, and encourage them to be pragmatic in their approach. The strategic significance of inhibitor products to meeting climate emission and environmental targets warrants increased flexibility and pragmatism in the registration of these products, while ensuring risks are effectively managed. We also encourage MPI to consider what other products could have lower efficacy requirements without compromising risk management.

Assessment of recommendation's impacts and implementation

Reducing efficacy requirements where not required to effectively manage risks would make the regulatory system more proportionate and may have some limited efficiency benefits. Improved clarity on how different claims affect efficacy requirements may improve transparency and certainty. Efficacy requirements should not be reduced in a way that substantially reduces the effectiveness of risk management.

Implementing recommendation 5 (increase the use and better design of group standards) and discussions between the EPA and industry may also reduce the burden of managing inhibitors within the HSNO system and improve timely access.

This recommendation would have a high impact for inhibitor products (and therefore end users who use them – see Chapter 4 for a quantitative impact assessment of a scenario where access to novel methane inhibitor is delayed). As an operational change and given MPI has already provided advice to the Minister for Food Safety and Minister for Agriculture on operational improvements to streamline registration for inhibitors, it should have low complexity to implement.

Recommendation 7: Recommend that the EPA and NZFS maximise their use of assessments by international regulators for assessing the risks of a product while still considering aspects unique to New Zealand

This recommendation relates to findings associated with New Zealand's competitive disadvantage, enabling timely access to products, approval path's speed and certainty, efficient and proportionate regulations, and regulator capacity and resourcing.

Both regulators have scope to increase their use of international regulators' information. There is a need for flexibility to ensure that decisions inappropriate for New Zealand are not directly adopted. However, regulators should start from a position that recognised international regulators' decisions are sound and focus on any New Zealand-specific considerations or risks. Clear definitions on what requires New Zealand-specific assessment are needed for transparency and consistency.

The EPA/HSNO

While the 2022 HSNO Act amendments which introduced international regulator amendments are still being implemented, and their full benefit has not been realised yet, we expect use of this pathway to continue to increase.

Assessment of recommendation's impacts and implementation

We consider there is an opportunity to go further than the existing legislation and consider clarifying in legislation or the Methodology Order that the EPA is able to rely on international regulators' assessments where these are likely to be appropriate for New Zealand. Clarification on what specific assessment is needed for the New Zealand context and how the use of international assessment should reduce the work performed by EPA assessors. This may support the regulator to have more confidence when using information from overseas regulators, as it would be clear that the law makers have accepted the intrinsic risk involved.

Flexibility in the use of information from international regulators is needed to avoid perverse outcomes, for example not considering specific New Zealand context and approving a product harmful for New Zealand. However, flexibility also provides regulators the opportunity to not use them to the fullest extent possible.

This recommendation can support improved proportionality and efficiency. If there is clear policy outlining how information from international regulators will be used, and when, this would improve transparency and certainty.

The impact of this recommendation could be low to moderate, as the EPA already uses information from international regulators for many applications. However, any improvements will have significant impact given the EPA queue and processing time.

NZFS/ACVM – NZFS use of international regulators' information in general

NZFS currently makes very limited use information from international regulators. We recommend NZFS to make better use of international regulators' work, where appropriate for New Zealand. This would enable New Zealand resource and expertise to be focused on risks or factors that are unique or of particular concern to New Zealand.

Assessment of recommendation's impacts and implementation

In the short term, NZFS may be able to give effect to this through administrative changes. We consider there may be value long term in providing clarity in the legislation that an overseas regulator's approval is a sufficient alternative to the requirement in section 20(a) of the ACVM Act to *"have regard to all relevant scientific and technical information"* or amending to be more outcomes based. This may provide reassurance to NZFS that the law makers accept the intrinsic risk of relying on international regulators' assessments, and therefore support NZFS to take a pragmatic approach.

MPI and NZFS should advise Ministers whether legislative change is needed to enable this, or whether it can be done administratively.

This recommendation could improve efficiency and proportionality by focusing resource on risks of most relevance to New Zealand. Guidance or operational policy on how international regulator information is used would support transparency.

This recommendation is expected to have moderate to high impact, as there is currently minimal use of information from overseas regulators. However, New Zealand's differing production patterns could limit the extent to which these can be used, without reducing effectiveness.

NZFS/ACVM – Non-food products pathway

Products used in non-food producing animals and plants do not pose trade and dietary exposure risks. Their usage pattern as well as production are likely to be identical to overseas, for example, companion animal veterinary medicine. We recommend a streamlined approval pathway for these products, where they have been approved by recognised overseas regulators.

It is critical that there are sufficient and robust constraints to ensure the work of overseas regulators is appropriate for New Zealand and will not have harmful impacts. This was very important to end users and environmental groups we met with. We envision that if the requirements were met, the ACVM assessment would be focused on the product data sheet and label. However, the full data package and overseas regulators' reports would need to be provided in case there is a need to verify certain aspects such as in the overseas regulator reports and/or for product data protection purposes.

Future variations and renewals could either be assessed by NZFS directly, or by recognising changes by the overseas regulators, following an application from the applicant. This pathway applies to approval under the ACVM Act, so does not

provide efficiencies for HSNO approvals. As most veterinary medicines may be approved under existing EPA group standards, many of the products in this pathway would not require a separate HSNO approval.

Assessment of recommendation's impacts and implementation

This recommendation would have improvements for efficiency, transparency and certainty for the manufacturers and importers of these products and be more proportionate given these products have less relevant risks. It would also provide some general efficiency gains, as regulator resource could be reprioritised to assessing products with risks that are more specific to New Zealand.

MPI should provide advice to Ministers regarding whether this is best achieved through regulatory or administrative changes.

This would have a high impact for products not being used in the food supply (that are not currently exempt), however this represents a small group of products. This would allow NZFS to direct further resource towards other products, and therefore could deliver a moderate impact overall. The complexity to implement would depend on whether legislative or operational pathways are chosen. If legislative, this would be moderate to high.

Recommendation 8: Recommend that the EPA and MPI (including NZFS) prioritise engagement at the international level to support harmonisation of requirements

This recommendation relates to findings associated with New Zealand's competitive disadvantage, enabling timely access to products, approval path's speed and certainty, efficient and proportionate regulations, and regulator capacity and resourcing.

We recommend that international engagement is continued to be prioritised by agencies, to learn from other regulators, ensure New Zealand practice is aligned, and continues to be aligned with overseas jurisdictions. International engagement should also prioritise the setting of evidence based MRLs, facilitate labelling harmonisation and enable products approved in New Zealand to be effectively used in New Zealand. This is important for maintaining an efficient and effective regulatory system and ensuring New Zealand requirements are proportionate and not an undue burden over and above other regulators.

Assessment of recommendation's impacts and implementation

The APVMA publishes an international engagement strategy which sets out their approach to international engagement, and notes that *"As a relatively small market for agvet chemicals, effective partnerships with other regulators provide the best opportunity for safe and effective chemicals to be available in Australia when they are needed. They also provide opportunities to enhance the capability and skills of APVMA staff through participation in international activities and sharing knowledge."* (Australian Pesticides and Veterinary Medicines Authority, 2022). Given New Zealand's market is even smaller than Australia's, this is even more true for New Zealand. There may be value in developing and publishing a similar document, providing transparency on the international engagement regulators are undertaking, and what the objectives of engagement are. The Sector Leaders Forum could highlight specific issues or challenges that are a priority to address through international engagement.

This recommendation supports improved efficiency, effectiveness and proportionality of the approval path. We note this may have resourcing or funding implications for agencies.

We estimate this recommendation will have a high impact. International harmonisation of requirements reduces regulatory burden and makes it more attractive for manufacturers to bring their products here. Influencing international MRLs supports end users to be able to better use approved agricultural and horticultural products. International labelling harmonisation, especially with Australia, has the potential to save significant costs for applicants. Agencies already do work in this space but may require further resourcing to increase the impact.

Recommendation 9: Recommend that MPI (including NZFS), MfE and the EPA explore a strategic priority pathway, in addition to the current first come, first served queue

This recommendation relates to findings associated with enabling timely access to products, approval path's speed and certainty, proportionate regulations, and regulator capacity and resourcing.

We discussed the merits of a strategic pathway, which can reduce opportunity costs by enabling high priority applications to commence assessment faster, in section 3.5. While the Australian Government has opted not to progress this approach, we consider the idea has some merits and should be explored further in a New Zealand context, given the current challenges with the EPA queue. We acknowledge there are challenges to such an approach, and ultimately may not be practicable.

We recommend that agencies (with the feedback from the Sector Leaders Forum) explore a potential priority pathway for determining applications to be prioritised. These criteria should be reviewed frequently and could be applied until the EPA queue has significantly reduced in size. It would be up to the applicant to

provide evidence that they meet the criteria, and it would be at the discretion of the regulator whether to grant the application strategic priority status (and explain their decisions). We note that the EPA has commenced work on developing such criteria, and that there are challenges in managing the competing views of a broad range of stakeholders. The Sector Leaders Forum should help mediate competing views.[79]

Criteria should be developed with collaboration across agencies, so that applications that require approval from both regulators can receive equal priority across both regulators.

Assessment of recommendation's impacts and implementation

This recommendation would improve proportionality by providing a mechanism to reduce the greater opportunity cost associated with some applications. This would improve efficiency for the system as resources will be prioritised on applications that will have the most benefits for end users and New Zealand as a whole. It may cause some delay and inefficiency for other applications, and there may be inefficiencies if regulators and applicants do not agree on the priority of a product or substance.

The impact of this recommendation depends on the design of the pathway, but we consider it to be moderate to high. Despite being operational, there is moderate complexity in developing robust and equitable criteria.

5.3.5. Recommendations to improve regulator resources, framework, and models

Recommendation 10: Recommend that the EPA update their outdated risk assessment models and consider how to keep them up to date for the future

This recommendation relates to findings associated with the EPA's risk assessment models.

The EPA's risk assessment models are outdated and no longer fit for purpose. This is a barrier to the EPA being able to regulate smarter and more efficiently.

We note that updating risk assessment models requires significant capital investment, and ongoing costs to keep them up to date and fit for purpose. Given the costs involved, consideration should be given to whether internationally available models could be adapted for New Zealand specific climates, or whether more value could be obtained from developing New

[79] We considered prioritisation forums where end users could determine for themselves what was of most significance. It would not be feasible to hold such prioritisation forums frequently enough to decide what applications should be prioritised directly, but there may be an opportunity for end user-led development of criteria which are updated periodically.

Zealand specific models. New Zealand specific models would be more costly, however, any need to 'interpret' the results of the models' output that is required when using overseas models may reduce the efficiency benefits of internationally adapted models. The most cost-effective solution to addressing outdated models should be progressed.

Assessment of recommendation's impacts and implementation

Modern and fit for purpose tools are essential for the efficiency of a regulator. Investing in modern risk assessment tools would enable improved efficiency, effectiveness, transparency, and certainty, and would support more risk proportionate controls being applied to products. This would be key to the Government's goal to 'regulate smarter' and be an attractive destination for overseas manufacturers and importers to sell their new products. Long term, updated models that can be made publicly available may unlock further efficiencies within the HSNO system.

This recommendation would have a high impact. There are significant costs associated with updating and maintaining models and this would depend on whether New Zealand specific models are generated, or whether models of overseas regulators could be adjusted for the New Zealand context. Updating the models is a high priority for the regulatory system overall, however it would take time to implement and see the benefits.

Recommendation 11: Recommend that MfE and the EPA review HSNO cost recovery provisions. We recommend that consideration be given to (but options should not be limited to):

- **whether the current level of cost recovery from industry is appropriate; and**
- **an annual levy to support general regulatory functions which do not provide applicant specific benefits.**

This recommendation relates to findings associated with enabling timely access to products, approval path's speed and certainty, and regulator capacity and resourcing.

In Chapter 3, we discuss the EPA's costs recovery levels and stakeholders' feedback relevant to efficiency and transparency in uses of funding, including funding from any increased costs recovery. We recommend MfE and the EPA consider whether the level of cost recovery from industry is appropriate with input from a wide range of perspectives.

As outlined in section 3.4.2, the EPA has outdated risk assessment models. The Auditor-General's and the Treasury's Guidelines on the setting of fees and levies include that capital costs required to provide services (such as risk assessment models) can be cost recovered, generally through depreciation of such assets following initial government investment

and set up. Whether to recover such costs will need to be carefully considered as part of any cost recovery review, including whether these models are used for other purposes.

Given New Zealand's small market size, consideration will need to be given to whether increased cost recovery would disincentivise manufacturers from registering products in New Zealand and if savings in processing time would justify any increases in approval costs. Whether changing or retaining the current cost recovery levels or limiting their increases would require a robust cost recovery analysis and input from the Sector Leaders Forum, stakeholders and the public. This would ensure that the process reflects cost recovery best practice, including transparency and efficiency and that increased costs recovered would be used to meet the needs of stakeholders and demonstrate value for money. This may involve developing new performance metrics that can be reported against, to support improved transparency and rebuild confidence (as discussed in Recommendation 13).

Increased cost recovery would not address all resourcing issues (Martin Jenkins, 2022). However, it "*might help to ease some of the pressure on the EPA's HSNO system, particularly where revenue from fees can be invested in the system itself (and all its components)"* (Loan, et al., 2023, page 40). Our other recommendations identify opportunities to use regulator resources more efficiently, by relying on the work of international regulators where appropriate and streamlining lower risk products.

We also discussed the potential merits of introducing an annual levy to support general regulatory functions which do not provide applicant specific benefits. We recommend MfE and the EPA explore this option.

Assessment of recommendation's impacts and implementation

Depending on the outcomes of the cost recovery review, it could improve proportionality and transparency. Investing cost recovered funds in improved tools like risk assessment models could improve efficiency and effectiveness. Any cost recovery increases would need to be accompanied by other recommendations to improve transparency and efficiency. Any additional fees or levies would need to comply with relevant international obligations.

There is a high level of uncertainty on the impact of this recommendation, as it depends on the outcome of the review. It has the potential to be moderate to high. The complexity of this recommendation is high. We consider this recommendation should be progressed following other changes to improve transparency, efficiency and proportionality.

Recommendation 12: Recommend that MPI strengthen the framework overseeing independent data assessors

This recommendation relates to findings associated with New Zealand's competitive disadvantage, enabling timely access to products, approval path's speed and certainty, proportionate regulations, and regulator capacity and resourcing.

As discussed in Chapter 3, there is no robust oversight of the ACVM independent data assessor model. To address concerns about the variable quality of assessors and mitigate duplication of work between independent data assessors and NZFS, that results from a lack of confidence in the assessments being undertaken, the framework and oversight of data assessors should be strengthened.

This may include more frequent training and calibration workshops with independent data assessors, and more active management of those who are listed. Consideration should be given to whether legislative mechanisms would provide additional benefits over and above administrative approaches.

Assessment of recommendation's impacts and implementation

We expect this recommendation would have a high impact, and would improve efficiency, transparency and certainty of the ACVM process. The complexity and resources required to implement depends on whether legislative change is required (high), or whether it can be implemented administratively (moderate).

5.3.6. Recommendations to improve regulator engagement and communication

Recommendation 13: Recommend the EPA and NZFS improve their performance reporting and MfE and MPI review statutory timeframes in their respective legislation

This recommendation relates to findings associated with speed and certainty of the approval path and regulator engagement and advice to applicants.

Current performance reporting across the approval path is disjointed and inconsistent. There is no performance reporting to show expected timeframes through both regulators or even a process map through both regulatory systems. We recommend agencies prioritise improved performance reporting, including using the Sector Leaders Forum advice to ensure indicators work well, for example, reporting on the EPA queue, support rebuilding trust between regulators and regulated parties and provide transparency. Performance reporting should reflect the full applicant experience, and therefore include time from submission of application to decision. We note that the EPA has recently provided more granular reporting on HSNO applications including the number of

applications in the queue, and that NZFS provides monthly updates on the number of applications in the queue.

Ministers may request specific performance indicators (in addition to those discussed in recommendation 3), and performance against these indicators should be reported transparently, including through the Sector Leaders Forum. There may be value in some joint performance indicators, to promote collaboration across the approval path.

Current statutory timeframes are not reflective of reasonable time needed to assess applications and are inconsistent with international statutory timeframes. This means they do not serve their intended purpose of providing transparency and setting clear expectations.

We recommend that existing statutory timeframes be reviewed and replaced with new timeframes, and improvements made to broader performance reporting. New statutory timeframes should differentiate between applications of varying complexity, capture the realistic staging of applications, acknowledge time in the queue and clarify under what circumstances time waivers or 'clock stopping' occurs.

Assessment of recommendation's impacts and implementation

While updated statutory timeframes would not improve the efficiency or effectiveness of the regulatory system, it would improve the transparency and certainty for applicants. It may support Ministers and stakeholders to better understand the performance of the approval path. The opportunity costs of inaccurate business plans are a regulatory burden, and therefore improved clarity and planning can enable a more proportionate regulatory system.

This recommendation would have a moderate to high impact in improving transparency. Amending statutory timeframes will take time and can be built into longer term legislative reform projects. Updating performance reporting can be done operationally and be done quicker. This recommendation does not directly reduce the queue.

Recommendation 14: Recommend that the EPA and NZFS prioritise the provision of up-to-date guidance, pre-application support, and transparency on application processing

This recommendation relates to findings associated with approval path's speed and certainty and regulator engagement and advice to applicants.

Guidance is key to how applicants and regulated parties engage with and understand the regulatory system. In the context of the ACVM and HSNO regulatory systems, it is also critical to how manufacturers and importers prepare their applications, including what data and information they generate. High quality applications would reduce the risk of putting applications on hold for additional

information and lengthening the assessment process. It also supports their business planning.

To avoid regulatory capture, it is inevitable that pre-application support available from regulators may not go as far as applicants would prefer, and services such as consultants will continue to have a place. However, we consider that there is scope for NZFS and the EPA to increase their provision of pre-application support, including by publishing guidance setting out what support regulators are able to provide, and where consultants may be needed. Regulators should also provide applicants with information on where their application is at with processing and guidance on expected timeframes.

Assessment of recommendation's impacts and implementation

Updated guidance including consistency across ACVM and HSNO systems where appropriate and improved pre-application support would enhance efficiency by enabling better quality applications. It would also improve transparency and certainty. Consideration should be given (as part of recommendation 8) to ensuring that requirements, and therefore guidance are harmonised to the extent practicable with overseas regulators.

Updated guidance would have moderate impact. However, updating guidelines can require resources to be directed away from assessing applications, and therefore, would take moderate time and resources to achieve.

Prioritising preapplication support and communication with applicants will likely have resourcing implications, which could impact on processing of applications and approval timeframes. We note that NZFS, and overseas regulators such as Ireland Pesticide Registration Division and APVMA charge specific fees for pre-submission or pre-application advice and meetings, which can mitigate resourcing implications.

Implementing this recommendation would have low to moderate impact, as agencies already provide some preapplication guidance, and there are limits to how much can be provided without causing regulatory capture or conflicts of interest.

Recommendation 15: Recommend that NZFS and the EPA extend existing stakeholder engagement forums to operate across both regulatory systems

This recommendation relates to findings primarily associated with the complex interface issues, regulator engagement communication, strategic direction and other issues.

While there are existing engagement forums which we received some positive feedback about, there was significant feedback that indicates there was a lack of mutual understanding between the regulators and regulated parties. These engagement forums do not operate jointly across both regulatory systems and could

be improved and expanded. The purpose of these forums is for broader and more operational engagement than the Sector Leaders Forum.

Assessment of recommendation's impacts and implementation

Improved understanding and communication between the regulators and regulated parties through such forums would improve transparency and certainty of the approval path. It would also support the effective implementation of other recommendations of this Review. Extending these forums would have resource implications, which should be discussed with Ministers.

We estimate the impact of this recommendation to be medium. Given the existing stakeholder forums, we consider the resources should be able to be repurposed. While there would be short-term resourcing implications to implement, long-term resourcing should be similar to the *status quo.*

Recommendation 16: Recommend that MfE review the emergency approval provisions under the HSNO Act, including better enabling products to be approved for biosecurity responses

This recommendation relates to findings associated with enabling timely access to products (competitive disadvantage), approval path's speed and certainty, proportionate regulations, and regulator capacity and resourcing.

The HSNO Act provides a faster assessment process for products approved in emergency situations. This pathway has not been as well utilised as intended, as it requires a responsible Minister to declare an emergency or special emergency. We have not been able to establish whether this is primarily a practice or legislative design issue. The fact that there have been no applications for products used in biosecurity emergency in the last several years and stakeholders and submitters were of the view that they could not use this tool suggests there is an opportunity to improve the utilisation of this pathway.

Assessment of recommendation's impacts and implementation

Consideration could be given to a provision similar to section 8C of the ACVM Act which refers to special circumstances at the discretion of the Director General. A review may determine that better guidance and understanding of HSNO emergency processes across other agencies may be sufficient to improve the use of this pathway, or that tools such as 'provisional approvals' for emergencies may work better.

Improvements to the emergency provisions would enhance efficiency for applications involving products needed in emergencies and reduce the opportunity costs associated with delays in approval, for example the impacts of a pest or disease becoming entrenched.

We consider the likely impact of this recommendation to be moderate. While it only applies to a small number of products or applications, it is where the most significant opportunity costs of regulation can sit. The complexity of implementing this recommendation would vary from high (if legislative change is required) to low/medium (if operational solutions can be identified).

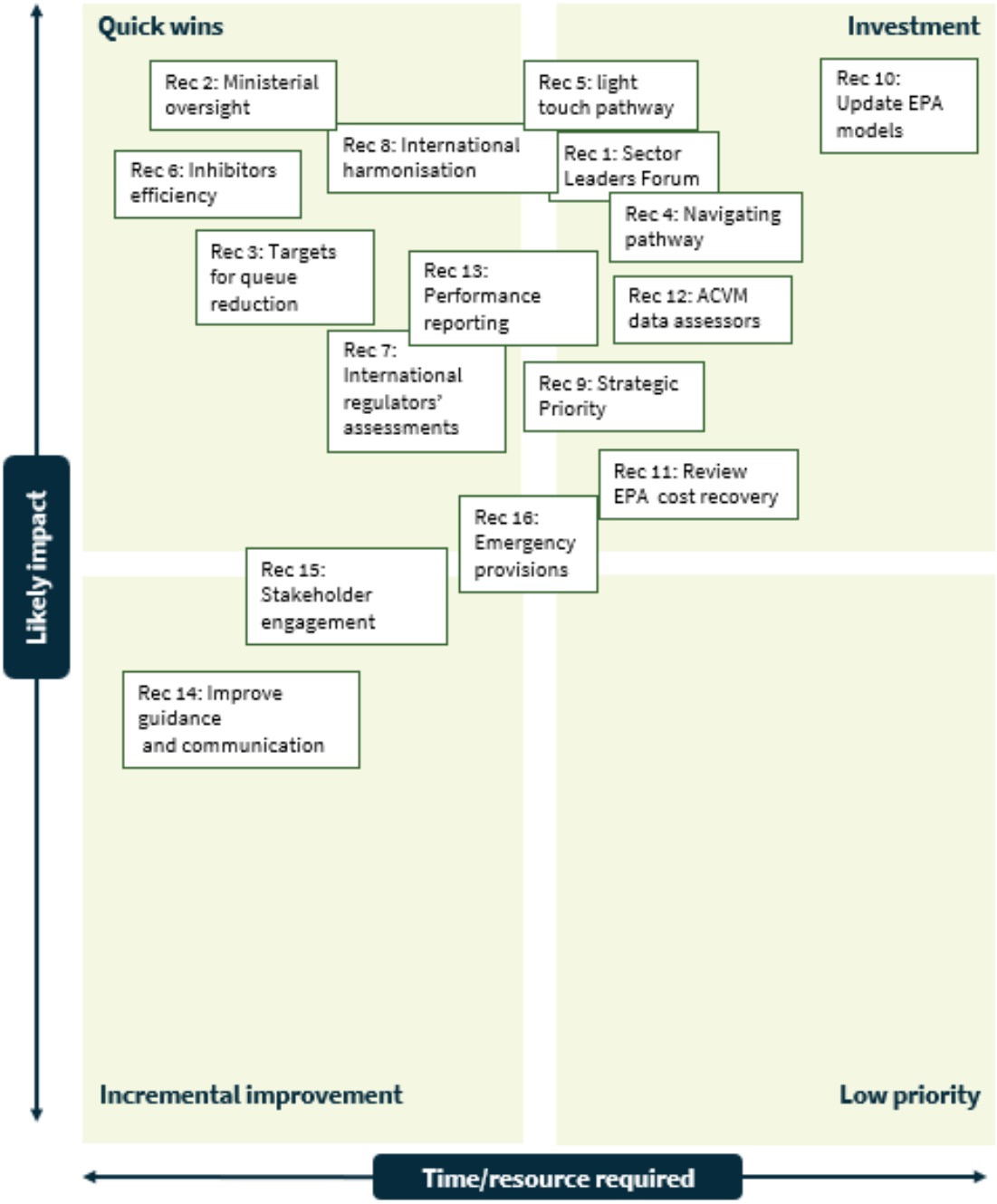
5.3.7. Summary of the impacts of the Review's recommendations and resources requirements for implementing them

Figure 7 shows our qualitative assessment of the scale of the impacts and complexity to implement the Review's recommendations. These may change as responsible agencies further develop the proposals and consider alternate approaches to achieve their intended outcome. During the Review process, we have considered a wide range of options. Many of them have not been recommended after careful analysis that has considered a range of perspectives. Appendix 3 lists some notable options that we have considered but not recommended.

The following four recommendations should be addressed as a matter of priority to support reducing the application queues:

a. recommendation 1: establishing a Sector Leaders Forum;
b. recommendation 5: improving the proportionality of the approval path by using more light-touch assessment pathways;
c. recommendation 7: increasing the reliance and use of assessments by international regulators; and
d. recommendation 10: updating the EPA models.

Figure 7: Impacts and complexity to implement the recommendations



5.3.8. Noting a non-regulatory opportunity

Support for the registration of products for minor crops

This opportunity relates to findings associated with enabling timely access to products (competitive disadvantage), speed and certainty of the approval processes, complex interface issues, and the engagement and advice provided by the regulators to applicants and stakeholders.

We discussed in Chapter 3 the challenges faced by New Zealand growers of 'minor crops' not being able to use some products available on the market due to the relevant registration and approval restrictions, limiting their use for certain crops. One of the most impactful ways that overseas jurisdictions have enabled access to products is through 'minor crop' or 'minor

use' programmes. These programmes provide financial support to generate the data needed to register products for use in minor crops. This direct conversation between minor crops grower groups and manufacturers highlights the growers' needs (for example, priority pest pressures) and highlights products and uses of products that companies have registered or are exploring in overseas markets.

While this is outside the scope of our recommendations, we note that evidence from overseas indicates it could be a cost-effective way to improve timely access to products and uses of products, particularly for the horticulture industry, as New Zealand horticulture crops are considered 'minor crops' internationally. We note that there could be an opportunity to consider similar programmes in New Zealand, potentially through the Sustainable Food and Fibre Futures fund (noting that this is a contestable fund subject to availability and eligibility criteria), or partnerships with levy groups. The design of any such programme would need to be in line with New Zealand's international obligations.

A review of the Australian Initiative estimated a return of 117 AUD (124 NZD, 2020) per grant dollar over 20 years (Eather, et al., 2020). Reports of similar programmes in the USA show an average return of about 225 USD (355 NZD, 2022) per dollar invested (Miller and Mann, 2022). An evaluation of the Canadian Minor Use Pesticides Program estimated that every dollar invested in the program returned 42 CAD (47 NZD, 2018) of net benefits to society (Office of Audit and Evaluation, 2018).

5.4 Other work underway by agencies

While these are not the Review's recommendations, we note and encourage the continuation of work underway by agencies that support improved access to products or the effectiveness of the regulatory systems.

5.4.1. Regulatory stewardship and maintenance

Well-functioning regulatory systems are important to New Zealanders. Ongoing regulatory stewardship – governance, monitoring and care of regulatory systems – is important to ensure the regulatory system remains fit for purpose now and into the future. Regulatory stewardship is critical to maintaining an efficient, effective, transparent and proportional regulatory system.

Many, if not all, of the issues or challenges examined in this Review have been known to agencies, but they have not been able to address them due to competing priorities and trade-offs that need to be made within limited resources and legislative agendas. We note agencies have all undertaken improvements and regulatory stewardship where possible to support the systems. These include developing new group standards, updating registration exemptions, and updating new guidance.

Where feasible and possible, we encourage agencies to take a proactive approach to regulatory stewardship. This will ensure that the regulatory system remains fit for

purpose for the future. We have identified some opportunities for agencies to consider as part of future regulatory stewardship. These are long term, lower priority improvements.

- **Managing the queues:** We understand that the EPA is exploring solutions to manage the queue size, including addressing incomplete applications that take up spaces in the queue but cannot be progressed (in addition to the measures mentioned in recommendations 5 – rapid pathways and 9 – prioritisation).
- **Reviewing the HSNO Methodology Order and design**: Given the Methodology Order has not been substantially amended since its introduction in 1998, it would be appropriate to review this. There may be opportunities to consider matters mentioned in Chapter 3 relevant to the Methodology Order. The methodology could be made as a Ministerial notice rather than through an order in council. This can save some time and resources while ensuring that the Minister is still involved, and the public has a say in setting the methodology as intended by the House of Representatives.
- **Benefits and least cost approach to regulation**: all regulators are expected to regulate in the most cost-effective way, and this expectation is demonstrated in the HSNO and ACVM provisions relevant to group standards and exemption regulations. Both HSNO and ACVM Acts require a consideration of benefits in decision making. There is likely an opportunity to provide further clarity on what these benefits are, and how they should be considered, as outlined in Chapter 4. There may be an opportunity to amplify the 'least cost approach' to managing risks to the purpose statement of the Acts, Methodology Order, or operational guidance.
- **ACVM light touch assessment pathways**: There is no ACVM legislative pathway for products and applications that require some level of assessment prior to authorisation but may not warrant the same level of assessment as more complex or risky products and applications. Currently, this is managed administratively, but there could be value in considering whether legislative pathways would provide greater transparency and certainty for these products and applications. This could include some types of biological products, or innovative animal feeds. We note there are differing risk levels within these categories of products.
- **Aligning with any relevant gene tech reform:** We encourage MfE and the EPA to consider whether there are opportunities to align HSNO regulatory system and practice with gene technology regulations, to provide operational and process efficiencies.
- **Monitoring, compliance, and enforcement**: The scope of this Review excludes monitoring, compliance, or enforcement. These are important aspects of a risk proportionate system and should be maintained and kept fit for purpose.

5.4.2. Implementation of the recommendations of the MPI Inspector General's report into the ACVM regulatory system

In June 2021, MPI Inspector General Regulatory Systems published a report examining the ACVM regulatory system. This review found that while the system is complex, it remained effective and fit for purpose and achieved the risk management objectives of the system. The Inspector General's report identified areas for improvement relating to governance and regulatory policy, and to four areas of regulatory delivery.

While some aspects of the Inspector General's findings were outside the scope of this Review, in general, the findings and areas for improvement align with this Review's findings, including issues relevant to statutory timeframes and updating exemption regulations.

We note that NZFS and MPI have undertaken significant work to address the Review's findings in recent years, and this has contributed to improved processing times and regulatory outcomes. We note some work has been unable to progress due to ministerial and organisational priorities and encourage NZFS to continue to progress work to address the findings of the Inspector General Regulatory Systems' report.

5.4.3. Implementation of the recommendations of the Parliamentary Commissioner for the Environment's Report

In March 2022 the Parliamentary Commissioner for the Environment published a report *Knowing what's out there - Regulating the environmental fate of chemicals.* The report made a range of recommendations, some of which align with the recommendations of this Review, including improved risk assessment models, and other recommendations which are outside the scope of this Review, such as relating to ongoing monitoring.

We note that MfE and the EPA initiated work on a number of these recommendations, but that these have resourcing and funding implications to progress. Some work, such as amendments to the importers and manufacturers notice has been delivered. Continuing to progress work to address the recommendations of this report will support improved effectiveness of the regulatory system.

5.4.4. Lifting staff capability through recruitment and training

Capable regulator means that the regulator has the people and systems necessary to operate an efficient and effective regulatory regime (The Treasury, 2012). A key indicator is that capability assessments occur at regular intervals and are subject to independent input or review.

Internationally, all comparable regulators face challenges arising from global shortages of qualified staff, and difficulties retaining skilled staff due to labour movement into the private sector. The staff working on assessing applications and engaging with applicants require specific expertise. Some of this is academic training (for example, toxicology expertise) and other aspects require on the job training. Undertaking staff training often requires more senior staff to be redirected

away from their core duties, which can impact on efficiency.

Issues raised by stakeholders and regulators show the difficulty that regulated parties can experience when new staff come on board and can make inconsistent recommendations to decision makers or provide inconsistent advice to applicants. This is an ongoing challenge that regulators will need to continually prioritise.

Regulatory stewardship and maintaining fit for purpose regulatory systems also requires sufficient policy staff capability and capacity. As noted earlier, limited resources and legislative agendas can impede updating and maintaining regulatory systems.

5.5 Next steps

The following key steps need to be taken next:

a. **the Minister for Regulation**, **Minister for the Environment, and Minister for Food Safety** will jointly consider the findings and recommendations to determine which recommendations to propose for Cabinet endorsement;
b. **Cabinet** will decide which actions to invite responsible Ministers to progress, and any follow-up reports that may be required; and
c. **MPI (including NZFS), MfE, and the EPA** will respond to the direction and expectations of their Ministers by conducting robust policy and operational processes to support implementation.

To support Cabinet decision on the recommendations and the implementation of Cabinet agreed recommendations, Ministers will receive advice from agencies on work programmes to implement the Review's recommendations. The Ministry for Regulation will provide relevant advice to Ministers and agencies at appropriate points during implementation upon requests.

We expect that implementation plans and progress of implementing these recommendations should be transparently shared with the Sector Leaders Forum and provided to Ministers to enable accountability.

The Minister for the Environment and Minister for Food Safety are responsible for ensuring that agencies implement accepted recommendations and should consider what targets or performance reporting will support them in this.

5.6 Conclusion

Regulation plays a crucial role in maintaining a safe, healthy and vibrant economy and society. During this Review process we have found issues within the two regulatory systems and the approval path that have not been addressed in a timely manner and resulted in a break-down of trust and confidence between regulators and some regulated parties. The historical design of the approval path, limited resources for competing priorities and insufficient strategic direction to ensure regulatory efficiency are the three fundamental causes of many issues raised.

We have recommended changes that would address identified issues and prevent future problems while not causing costly disruption to the design of the approval path. We note the complexity of an approval path across the two regulatory systems will remain to some extent if New Zealand continues to choose this design and the competitive disadvantage will continue to be an ongoing challenge. However, as a package, the Review's recommendations would improve the proportionality, efficiency, transparency and certainty of the approval path.

Particularly, recommendations establishing a strategic approach and driving efficiency and proportionality would help the systems achieve the balance of effective management of risks and enabling timely access to products.

Ministerial oversight would ensure prompt implementation of this Review's recommendations and timely solutions for future issues.

Good regulatory practice requires government agencies to be proactive and collaborative to ensure the system adapts and responds to opportunities and changes and delivers regulation in a timely manner and minimise the compliant costs for regulated parties (MBIE, 2021, The Treasury, 2022).

We expect and stay positive that the implementation of the Review's recommendations will ensure that different parts of the two regulatory systems work together to achieve their goals and keep the systems fit for purpose over the long term.

We envisage more transparency and collaboration between regulators and regulated parties in the future, including sharing knowledge, initiatives, and evaluation of the regulators' performance and industry behaviours.

Glossary

ACVM	Agricultural Compounds and Veterinary Medicines
AICIS	Australian Industrial Chemicals Introduction Scheme
APVMA	Australian Pesticides and Veterinary Medicines Authority
EFSA	European Food Safety Authority
EPA	Environmental Protection Authority
EU	European Union
GAP	Good Agricultural Practices
GDP	Gross domestic product
HSNO	Hazardous Substances and New Organisms
MfE	Ministry for the Environment
MfR	Ministry for Regulation
MPI	Ministry for Primary Industries
MRL	Maximum Residue Level
NZFS	New Zealand Food Safety
USA	The United States of America
US EPA	United States Environmental Protection Agency

References

Abioinvestor. (2024). *Time and Cost of New Agrochemical Product Discovery, Development and Registration*. Time-and-Cost-To-Market-CP-2024.pdf (croplife.org)

AO, K.M. Astin, A. Corbett, M. & Suann, C. (2021). *Final Report of the Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia*. Canberra: Department of Agriculture, Water and the Environment. agvet-chemicals-review-final-report.docx (live.com)

Australian Industrial Chemicals Introduction Scheme. (2024). *Cost recovery for regulatory activities 2024-2025*. CRIS 2024-25_0.pdf

Australian Pesticides and Veterinary Medicines Authority. (2022). *International engagement strategy.* Sydney: Australian Pesticides and Veterinary Medicines Authority. https://www.apvma.gov.au/sites/default/files/publication/102176-international_engagement_strategy.pdf

Australian Pesticides and Veterinary Medicines Authority. (2023). *Strategic Review Report*. Canberra: Clayton Utz. APVMA - Strategic Review Report.PDF (agriculture.gov.au)

Australian Pesticides and Veterinary Medicines Authority. (2024a). *Consultation Paper: Cost Recovery Implementation Statement.* Sydney: Australian Pesticides and Veterinary Medicines Authority. CRIS 2025 - Consultation Paper.pdf (apvma.gov.au)

Australian Pesticides and Veterinary Medicines Authority. (2024b). *Draft Guidelines for Determining Minor Use.* Public Consultation. Sydney: Australian Pesticides and Veterinary Medicines Authority. Draft guidelines for determining minor use

CropLife International. (2012*). Initiatives and Schemes in Support of Minor Uses.* Belgium: CropLife International. Brochures-Overview-of-minor-use-initiatives-and-schemes-globally.pdf

Deloitte. (2019). *The future of agrochemicals*. us-eri-future-of-agrochemicals.pdf

Eather, J, Addai, D, Hafi, A & Gomboso, J. (2020). *Benefits of increased access to minor use chemicals*. Canberra: Department of Agriculture, Water and the Environment. https://doi.org/10.25814/5e2fc12d89c24

Environmental Protection Authority. (2013). *Monitoring the Effectiveness of the Hazardous Substances and New Organisms Act 1996.* Wellington: Environmental Protection Authority. *Monitoring-the-effectiveness-of-the-HSNO-Act-2013.pdf (epa.govt.nz)*

Environmental Protection Authority. (2018). *HSNO Fees Cost Recovery Impact Statement.* Wellington: Environmental Protection Authority. HSNO Act fees cost recovery impact statement (epa.govt.nz)

Environmental Protection Authority. (2019). *Statement of Intent 2019 to 2023.* Wellington: Environmental Protection Authority. EPA-Statement-of-Intent-2019-to-2023.pdf

Environmental Protection Authority. (2021). *Application report: reassessment of hydrogen cyanamide.* Wellington: Environmental Protection Authority. APP203974 Application report

Environmental Protection Authority. (2022). *Statement of Intent 2022 to 2026.* Wellington: Environmental Protection Authority. Statement of Intent 2022 to 2026

Environmental Protection Authority. (2023). *Amendments to Hazardous Substances (Importers and Manufacturers) Notice 2015 Discussion document.* Wellington: Environmental Protection Authority. Amendments to Hazardous Substances (Importers and Manufacturers) Notice 2015 Discussion document

Environmental Protection Authority. (2024). *Quarterly Report 1 July – 30 September 2024 Q1 2024/25.* Wellington: Environmental Protection Authority. https://www.epa.govt.nz/assets/RecordsAPI/Quarterly-performance-report-to-the-Minister-1-July-to-30-September-2024-Amended.pdf

Food and Agriculture Organization of the United Nations. (2024). *Pesticide Registration Toolkit – Checking for registrations elsewhere*. Rome: FAO https://www.fao.org/pesticide-registration-toolkit/information-sources/registrations-elsewhere/en/

Food and Agriculture Organization of the United Nations & World Health Organization. (2014). *The International Code of Conduct on Pesticide Management.* Rome: FAO and WHO. The International Code of Conduct on Pesticide Management

House of Representatives. (1996). *Parliamentary debates (Hansard).* Wellington: House of Representatives. Volume 554. Vol 554.pdf - Google Drive

House of Representatives. (1997a). *Parliamentary debates (Hansard).* Wellington: House of Representatives. Volume 559. Vol 559.pdf - Google Drive

House of Representatives. (1997b). *Parliamentary debates (Hansard).* Wellington: House of Representatives. Volume 564. Vol 564.pdf - Google Drive

Inspector General Regulatory Systems. (2022). *Regulatory Review Framework.* Wellington: Ministry for Primary Industries. 49123-IGRS-Regulatory-Review-Framework-September-2021.pptx

KPMG. (2021). *Assessing the value of the Animal Health Industry to New Zealand*. Wellington. Animal-Medicines-Report-July2021.pdf (animalplanthealth.co.nz)

KPMG. (2022). *ACVM Process and Resourcing Review.* Wellington: KPMG. Internal document.

Loan, J. & Woock, K. (2023). *The EPA's Role and Performance in Assessing Hazardous Substances*. Wellington: Sapere. Briefing-to-the-Incoming-Minister-for-the-Environment-December-2023-The-EPAs-role-and-performance-in-assessing-hazardous-substances.pdf

Martin Jenkins. (2022). *Functional and funding baseline review of the Environmental Protection Authority.* Wellington: Martin Jenkins. MartinJenkins-functional-and-funding-review.pdf

Miller, S R & Mann J T. (2022). *The Economic Impact of the IR-4 Project and Programs.* USA: Michigan State University. Microsoft Word - IR4 2022 Final.docx

Ministry of Health. (2021). *Medsafe Fees Review Consultation Document*. Wellington: Ministry of Health. Medsafe Fees Review - New Zealand Ministry of Health - Citizen Space

Ministry of Agriculture and Forestry. (2011). *ACVM Registration by Reference to APVMA Registration*. Wellington: Ministry of Agriculture and Forestry. MAF Technical Paper Template (mpi.govt.nz)

Ministry of Business, Innovation & Employment. (2021). *What regulatory system governance is and why it's important: principles and guidance.* Wellington: Regulatory Stewardship Branch, MBIE. What regulatory system governance is and why it's important

Ministry for Primary Industries. (2015). *Becoming a Data Assessor for ACVM Products.* Wellington: Ministry for Primary Industries. Template Requirements

Ministry for Primary Industries. (2016). *Data Protection for Agricultural Compounds, Regulatory Impact Statement.* Wellington: Ministry for Primary Industries. Data Protection for Agricultural Compounds - 8 September 2016 - Regulatory Impact Statement - Ministry for Primary Industries

Ministry for Primary Industries. (2018). *Supporting information for Cost Recovery at MPI. Findings from the First Principles Review of MPI's cost recovery arrangements.* Wellington: Ministry for Primary Industries. Supporting information for: Cost Recovery at MPI Findings from the First Principles Review of MPI's cost recovery arrangements.

Ministry for Primary Industries. (2021). *Agricultural Compounds and Veterinary Medicines Act 1997 – A Regulatory System Review*. Wellington: Inspector General Regulatory Systems. Agricultural Compounds & Veterinary Medicines Act 1997 – A Regulatory System Review (mpi.govt.nz).

Ministry for Primary Industries. (2024b). *Agricultural Chemical Registration Guidance Document*. Wellington: Ministry for Primary Industries. Agricultural Chemical Registration (mpi.govt.nz)

Ministry for Primary Industries. (2024c). *Situation and Outlook for Primary Industries.* Wellington: Ministry for Primary Industries. Situation and Outlook for Primary Industries June 2024 (mpi.govt.nz)

Ministry for Primary Industries. (2024d). *Stage 2 Cost Recovery Impact Statement.* Wellington: Ministry for Primary Industries. Stage 2 Cost Recovery Impact Statement: Ministry for Primary Industries' Cost Recovery Settings Annual Review 2024 - 31 May 2024 - Ministry for Primary Industries

Ministry for Primary Industries. (2021). *Protection of Confidential Information about Trade Name Products.* Wellington: Ministry for Primary Industries. Protection of Confidential Information about ACVM Trade Name Products ACVM guidance

Ministry for Regulation. (2024). *Regulation in New Zealand Quick Guide.* Wellington: Ministry for Regulation. RPE-Quick-Guide-Regulation-in-New-Zealand.pdf

Ministry for the Environment. (2015a). *Environmental Protection Authority Cost Recovery Practices – A component of the Review of the Effectiveness of the Environmental Protection Authority.* Wellington: Ministry for the Environment.

Ministry for the Environment. (2015b). *Environmental Protection Authority fiscal review.* Wellington: Ministry for the Environment. Environmental Protection Authority fiscal review

Ministry for the Environment. (2015c) *Review of the efficiency and effectiveness of the Environmental Protection Authority.* Wellington: Ministry for the Environment. Review of the efficiency and effectiveness of the Environmental Protection Authority

Ministry for the Environment. (2015d). *Self-review of the Environmental Protection Authority.* Wellington: Ministry for the Environment. Self-review of the Environmental Protection Authority

Ministry for the Environment. (2019). *Hazardous substances assessments: Improving decision-making – A discussion document on proposed improvements to assessments and reassessments of hazardous substances*. Wellington: Ministry for the Environment. Hazardous substances assessments: Improving decision-making - A discussion document on proposed improvements to assessments and reassessments of hazardous substances.

Ministry for the Environment. (2020). *Regulatory Impact Assessments on proposed amendments to the Hazardous Substances and New Organisms Act 1996.* Wellington: Ministry for the Environment. Regulatory Impact Assessments on proposed amendments to the Hazardous Substances and New Organisms Act 1996

Ministry for the Environment. (2020). *Policy approval for proposed amendments to the Hazardous Substances and New Organisms Act 1996.* Wellington: Ministry for the Environment. Policy approval for proposed amendments to the Hazardous Substances and New Organisms Act 1996

Ministry for the Environment. (2021). *Cabinet paper: Hazardous Substance and New Organisms (Hazardous Substances Assessments) Amendment Bill: Approval for Introduction.* Wellington: Ministry for the Environment. Cabinet paper: Hazardous Substance and New Organisms (Hazardous Substances Assessments) Amendment Bill: Approval for Introduction

New Zealand Food Safety. (2022). *A Strategy for New Zealand Food Safety. Strategy Refresh 2022 – 2024.* Wellington: New Zealand Food Safety, Ministry for Primary Industries. A Strategy for New Zealand Food Safety Strategy Refresh 2022-24

New Zealand Food Safety. (2024). *Application to Vary the Chemistry and/or Manufacturing Information for a Veterinary Medicine Trade Name Product ACVM 79 (Feb 2024)*. Wellington: New Zealand Food Safety. Application to Vary the Chemistry and/or Manufacturing Information for a Veterinary Medicine Trade Name Product

New Zealand Institute of Economic Research. (2019). *The Importance of Crop Protection Products for The New Zealand Economy.* Wellington: New Zealand Institute of Economic Research. NZIER-Report.pdf (animalplanthealth.co.nz)

OECD. (2014). *The Governance of Regulators*, OECD Best Practice Principles for Regulatory Policy. Paris: OECD Publishing. The Governance of Regulators

Office of Audit and Evaluation. (2018). *The Evaluation of the Minor Use Pesticides Program.* Canada: Agriculture and Agri-Food Canada's Office of Audit and Evaluation. Evaluation of the Minor Use Pesticides Program - agriculture.canada.ca

Parliamentary Commissioner for the Environment. (2022). *Knowing what's out there: Regulating the environmental fate of chemicals*. Wellington: Parliamentary Commissioner for the Environment. regulating-the-environmental-fate-of-chemicals.pdf (pce.parliament.nz)

Phillips, M. (2019). *Agrochemical industry development, trends in R&D and the impact of regulation*. Agrochemical industry development, trends in R&D and the impact of regulation - Phillips - 2020 - Pest Management Science - Wiley Online Library

Simmons, Penny. (2024). *2024/25 Letter of Expectations for the Environmental Protection Authority*. Wellington: Environmental Protection Authority. 2024/25 Letter of Expectations for the Environmental Protection Authority

The Environment Court. (2021). *Royal Forest and Bird Protection Society of New Zealand v Bay of Plenty Regional Council*. Auckland: The Environment Court at Auckland. 2021-NZEnvC-147-Royal-Forest-and-Bird-Protection-Society-of-New-Zealand-v-Bay-of-Plenty-Regional-Council.pdf

The High Court of New Zealand. (2001). *Claire Bleakley v Environmental Risk Management Authority*. Wellington: The High Court of New Zealand Wellington Registry. AP177/00

The High Court of New Zealand. (2010). *GE Free NZ in Food and the Environment Inc v Environmental Risk Management Authority*. Wellington: The High Court of New Zealand Wellington Registry. GE-FREE-NZ-IN-FOOD-AND-ENVIRONMENT-INCORPORATED-vJTK1947.pdf

The Treasury. (2012). *The Best Practices Regulation Model: Principles and Assessment.* Wellington: The Treasury. *The Best Practice Regulation Model: Principles and Assessments - July 2012*

The Treasury. (2022). *Starting out with regulatory stewardship: A resource.* Wellington: The Treasury. Regulatory stewardship | The Treasury New Zealand

Transport and Environment committee. (1997). *Agricultural Compound Bill*. Agricultural Compounds Bill 1997 (112-2)

Appendix 1: Detailed background information

1. Examples of food export incidents

Psa-V (Kiwifruit 2010)

First identified in 2010, Psa-V, a bacterial disease of kiwifruit vines, gradually spread to all the main kiwifruit growing areas of the North Island. The outbreak led to ACVM approvals for new products to fight the disease. DDAC, a compound used as an antiseptic/disinfectant, was found on organically certified kiwifruit. The compound contaminated a product that was sprayed on kiwifruit to fight Psa-V. The impacts included loss of access to premium markets, including Japan which has zero tolerance for the compound.

DCD (Dairy, 2013)

DCD (dicyandiamide) is a competitive inhibitor that slows the conversion of ammonium to nitrate, preventing loss of nitrates and providing more time for plant uptake of ammonium. While DCD is considered to have low toxicity, residues may be present in milk from animals that have grazed on pastures where DCD has been applied. In 2013, many countries had not established maximum residue limits for DCD.

Low levels of DCD residues, around 100 times lower than acceptable levels under European food safety limits at the time, were found by Fonterra in milk powder in September 2012, prompting MPI to suspend its use in January 2013. This led to a number of Asian markets raising concerns over New Zealand dairy products and increased and ongoing costs to the industry to test for DCD in dairy products.

Glyphosate (Honey, 2020)

Japan discovered glyphosate residues in honey during border testing in 2020. Apiculture New Zealand claimed that despite this, there were no food safety concerns at the levels detected. Based on threats that New Zealand honey imports may be rejected or banned, NZFS now requires all honey exports to Japan to undergo testing for glyphosate residues.

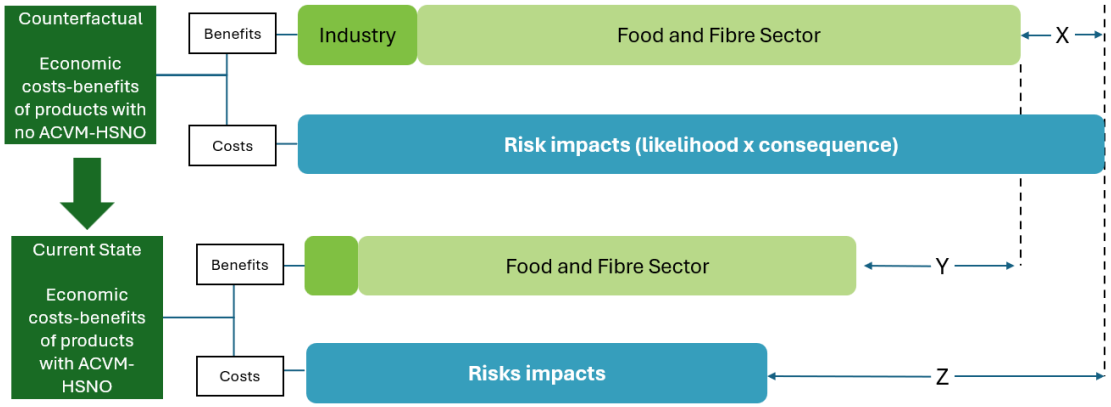
2. Benefits and costs of products versus benefits and costs of regulation

An important part of reviewing regulation is to ask why it exists. This can be helped by setting up a counterfactual: the absence of the ACVM-HSNO regulations for agricultural and horticultural products, including the approval path.

Under this theoretical scenario, it's assumed the community theoretically receives benefits from having unfettered access to these products in New Zealand. Apart from the economic activity generated by the industry, this includes the benefits to farmers and growers from

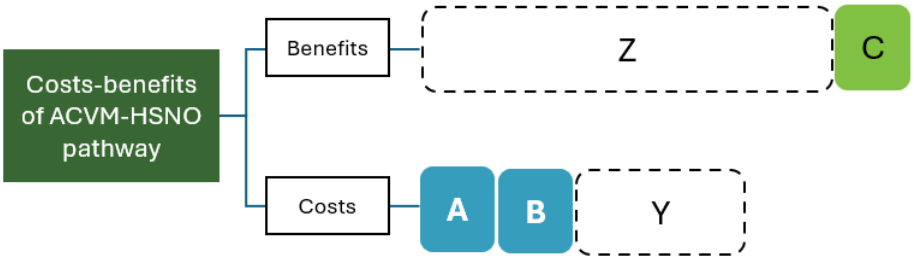
the increased productivity that agricultural and horticultural products provide the food and fibre sector.

But there are also potential costs, equivalent to the likelihood times the consequence of an adverse outcome occurring, such as harm to human health or loss of farmland. If the overall economic costs of the counterfactual (that is no regulation) are greater than the overall economic benefits, indicated by X in the figure below, then there is a case for government to intervene.



The economic costs and benefits of the products are different to the economic costs and benefits of regulation. In a sense, they are opposites. The purpose of the regulation is to reduce the risks to a level that achieves a net benefit for society. Doing this, helping to avoid harmful events and their flow-on effects, is the benefit of the ACVM-HSNO system. However, this comes at a cost. The restrictions placed on agricultural and horticultural products reduces their overall benefits, shown as Y in the figure above. There are also other costs from regulation, including administration (A) and the cost of government interference that distorts the market, leading to different prices and changed behaviour that then cause resources to be directed toward less productive areas of the economy (B).

In addition to reduced risk impacts (Z), the ACVM-HSNO pathway has specific benefits, shown as C. These include government-to-government trade arrangements and the use of efficacy information to assist with other objectives, such as biosecurity.



On the whole, other than in the case of C, the regulations do not “enable” the use of agricultural and horticultural products or promote their benefits. Regulations typically restrict their use. Regulation should minimise these costs for a given level of risk.

3. *Definitions of market failures*

Asymmetric information – markets can be ineffective if one party has significantly more information than the other. It is a particular problem if a buyer or seller uses this to conceal important information. This can be addressed by requiring information disclosures, such as those found on food labels.

Externalities – those who produce or consume a good or service can generate costs and benefits that fall on third parties. These externalities can be positive (for example, reduced transmission of infectious diseases from vaccinations) or negative (for example, pollution).

Market power – abuse of market power occurs when a single or small number of suppliers uses the absence of effective competition to raise prices or reduce services by limiting supply.

Public good – some goods have the special characteristic that their use does not reduce availability for others and/or it is not possible or practical to prevent another party from also using them. Examples of a public good include national defence and traffic management systems.

Club good – is a good that is non-rivalrous (that means the use of it does not reduce availability to others) but there can be exclusions, up to a point. Examples include toll roads and wireless internet.

Behavioural – people make poor decisions based on cognitive limitations and psychological biases that lead to poor outcomes. For example, a person may think they are a better driver than they actually are.

4. *Examples of co-regulation*, self-regulation, and non-regulation

Legislation/ initiative	Description	Comments
Veterinarians Act 2005	Veterinary Council of New Zealand is the statutory body responsible for upholding veterinary standards to protect people and animals, and to maintain trust in veterinary professionals.	Compulsory, legislative.
Fonterra	Cooperative Difference Program. Incentivising environmental improvements to achieve set targets: for example,	This is a framework for members of the co-op. *"The Co-operative Difference framework recognises farmers who have made positive changes and encourages other farmers to do the same. It identifies and considers*

	Fonterra has an ambition of being net zero by 2050, with 2030 targets including a 30% intensity reduction in on-farm emissions.	*what we need to do today, what we need to be thinking about for tomorrow and what we need to consider in the longer term."* Fonterra pays up to 10c per kilogram of milk solids above base milk price to farms that achieve practices across five focus areas – Milk, People and Community, Environment, Animals and Co-operative and Prosperity.
New Zealand's National Farm Assurance Programmes (NZFAP/NZFAP Plus)	Audited assurance programmes. To provide assurances regarding integrity, traceability, animal health and welfare, people, farm and natural resources and biosecurity.	Requires joining and agreeing to terms and audits: For NZFAP: agree to maintain your on-farm systems and procedures in full compliance with the requirements of the NZFAP Standard against which you are assessed. For NZFAP Plus: agree to maintain your on-farm systems and procedures in full compliance with the requirements of the NZFAP Standard and strive to be NZFAP Plus compliant well within the allowed 3-year period. NZFAP is not mandatory although most processors have NZFAP certification as a requirement in their terms and conditions of supply.
New Zealand Good Agricultural Practices - Horticulture New Zealand (GAP)	Audited assurance programme. Meets GLOBAL GAP requirements: • certification requirements for a range of customers in New Zealand and overseas; • aligned with NZ regulatory standards; and • includes standards for food safety, health and safety and environmental management.	NZGAP is an industry-good, not-for-profit business unit within Horticulture New Zealand. It provides a framework to meet local regulatory obligations and to supply fresh produce to New Zealand customers that require a GAP certificate. NZGAP is primarily funded via participant (certificate holders) annual fees. NZGAP acts as a conduit between growers, auditors, regulators, and markets to moderate and minimise compliance costs. Key functions include: • development and maintenance of standards and rules;

	NZGAP also provides guidance for growers, such as Guidelines for Off-label use of Agrichemicals.	• benchmarking and recognition of standards against regulatory and market requirements; and • information technology development including the NZGAP public register and integration with stakeholder systems. An environmental add-on can be used to demonstrate compliance with regional council rules for an audited Farm Environment Plan.
Beef and Lamb New Zealand Strategies	Industry strategies to improve farm performance	Beef and Lamb New Zealand is funded by farmers through commodity levies paid on all sheep, beef and dairy cattle processed in New Zealand. Commodity Levies (Meat) Order 2015 (LI 2015/307) (as at 17 December 2016) – New Zealand Legislation Strategies are developed in partnership with farmers and outline key priorities and how they will be achieved.
Processor company initiatives	Synlait. Miraka. Alliance. Silver Fern Farms. Typically, environmental / sustainability targets and roadmaps are set, with incentives to farmers.	Synlait – Lead with Pride – recognises and financially rewards suppliers who achieve dairy farming best practice (Certified Members). Miraka – Te Ara Miraka – values-based business and farming excellence programme: premiums based on improving sustainability, welfare, quality, and productivity. Alliance – publishes a Sustainability Roadmap Silver Fern Farms – Good by Nature – published sustainability plan.

Appendix 2: Detailed information supporting issues analysis

1. ***Assumptions used for describing the approval path and estimating the processing timeframes***

Applicants may file applications to the EPA and NZFS sequentially, in any order, or file them concurrently. The flow diagram in Chapter 2 and the estimation of processing timeframes in Chapter 3 of the report reflect a concurrent filing approach and are based on the following assumptions:

- New trade name product with at least one new active ingredient.
- Applicant submits an incomplete ACVM application and expressly states in their cover letter that they have done so to secure product data protection.
- Applicant submits a complete and assessable HSNO application very soon after submitting ACVM application.
- While awaiting HSNO assessment, applicant completes all required ACVM pre-application steps, including any NZ-specific trials and obtaining data assessment reports from an independent data assessor. Application rate approved by the EPA is the same as specified in the ACVM application. If this is not true, NZFS must reassess the application based on the EPA-approved application rate.
- No advice from the Ministry of Health is required.
- During public consultation, someone made a request to be heard (i.e. public hearing cannot be waived).

2. ***Examples of agricultural and horticultural products available overseas but not in New Zealand due to commercial decisions and regulatory barriers***

Sivanto Prime (flupyradifurone), an insecticide that can control sap-feeding pests that damage crops such as aphids, springtails, wheat bugs and whiteflies. This product was approved in Australia in 2016 after 4 years, and in other countries.

The application to the EPA lodged: 11/2020, formal receipt: January 2021, submissions closed: August 2024, hearing: planned for December 2024, decision: pending.

If the substance is approved by the EPA, it will need to obtain ACVM registration before being available on New Zealand market. We note there was a commercial decision to introduce the product to Australia (and other countries) several years before New Zealand.

The berry industry was interested in the ability to access to various botryticides products to rotate tools and reduce resistance. They also had concerns about not being able to use some botryticides products because of the default MRL, which is lower than MRLs set in other countries, such as Australia. Suppliers of these products have obtained EPA approvals but not for berries. This is likely due to commercial decisions. Some of them are

Luna Sensation (fluopyram/trifloxystrobin), Kenja (isofetamid), Miravis (pydiflumetofen). This is relevant to off-label uses for minor crops which are discussed in the report.

Other products the industry desires to have access to are Rhapsody/Migiwa (ipflufenoquin) and Versys/Sefina (afidopyropen) (in the EPA queue); Adevelt (florylpicoxamid) and Plinazolin (isocycloseram) (no applications made to the EPA yet).

The wine industry is waiting for HSNO assessment of Rhapsody (ipflufenoquin) and Yukon (tribasic copper and sulphur).

Other examples of substances under HSNO assessment Seclira (dinotefuran), Trifix (triflusulfun-methyl), Vibrance Premium Seed treatment (sedaxane), Reatis 480 FS and Vayego Duo

Substances containing acetamiprid are already approved under HSNO, but no application has been made to NZFS.

3. *HSNO and ACVM assessment processes*

HSNO assessment process for a hazardous substance containing a new active ingredient

Prior to lodgement of application

Pre-submission discussion(s) between applicant and EPA (if requested by applicant)
Applicant engagement with Māori

Lodgement of application

Applicant submits application
- Toxicology
- Ecotoxicology
- Environmental fate
- Chemistry (physical/chemical properties)

Application assigned to an advisor
Application checked for missing data/information and requested from the applicant
Assessment pathway determined and decision on public notification

Notification

Publicly notified applications are notified to:
- Minister for the Environment
- WorkSafe

Applications may be notified to other agencies as relevant, including MPI, DOC, MoH

Evaluation and assessment

EPA assess application and requests more information to determine and evaluate:
- Hazard classifications and endpoints
- Health-based guidance values (HBGV) and impacts on people
- Environmental endpoints and impacts on the environment
- Consideration of Māori perspectives
- Risks and benefits
- Controls required to manage risks

→ Health-based guidance values provided to ACVM

Public consultation and hearing

Publicly notified applications are open for 30 working days for public consultation and submission
- Any submitter may request to be heard at a hearing
- A decision-making committee (DMC) will hear submissions, request clarifications and/or additional information before considering of the application

Applications not publicly notified progress directly to consideration and decision

Consideration and Decision

Publicly notified applications decided by a decision-making committee (DMC), non-notified applications decided by EPA CE, either:
- Approve application and set controls to mitigate risks, or:
- Decline application if risks cannot be managed/insufficient information to determine risks
- Decision published on EPA website and databases

→ HSNO approval number required for ACVM to finalise approval

Post approval

Approvals exist in perpetuity unless a reassessment is undertaken. Possible triggers for reassessment include:
- EPA FRCaST tool and reassessments workplan
- Emerging issues list
- CME activities, incident reports and public complaints
- Decisions of international regulations
- Request for reassessment by external parties

Notes
1. EPA assessment does not require any input from ACVM and is completely independent.
2. Process relates to applications with new active ingredient(s) and quantitative assessment (Category C).
3. Other application types (rapid, Category A, Category B, containment) typically don't require notification, consultation, or hearing steps. Health-based guidance values are generally not required

Keys: blue denotes HSNO process, green denotes ACVM process

ACVM assessment process for a trade name product (TNP) containing a new active ingredient

Prior to lodgement of application

Pre-submission discussion(s) between applicant and ACVM
Applicant engages external data assessor to review data package

Notes
1. Application to ACVM may be alongside or before or after an EPA assessment.

Lodgement of application

Applicant submits application
- Chemistry and Manufacturing
- Good Manufacturing Practice (where applicable)
- Efficacy
- Target Animal and Plant Safety
- Residues

Application assigned to an advisor
Application checked for missing data/information and requested from the applicant
Decision on whether to make public notification on the application

Notification

Applications are notified to:
- Minister for Food Safety
- EPA and other agencies (as relevant)

Public notification notified in Gazette where required.

Evaluation and assessment

ACVM assess the application:
- Consider applicant's data package
- Consider public submissions and NZ international obligations
- Determine the level of risks in ACVM Act risk areas
- Determine benefits
- Make a recommendation on whether to grant or refuse

Health-based guidance values provided to ACVM for purposes of dietary exposure assessment in relation to MRLs set under the Food Act

Public consultation

Publicly notified applications are open for 30 working days for public consultation and submission. Submissions received are required to be sent to the applicant.

Consideration and Decision

The decision maker makes a decision to either:
- Refuse if risks cannot be managed or insufficient information to determine risks; or
- Grant approval and set controls to manage the risks that are at least cost to public
- If awaiting EPA approval, decision made within 5 working days of EPA decision
- If the product is also a prescription medicine under Medicines Act, then need Ministry of Health approval first.
- Decision notified to applicants and any submitters.
- Added to ACVM register

HSNO approval number required for ACVM to finalise approval but is not part of the assessment

Post approval

Grounds for reassessment are based on new information or change in use. Possible triggers for reassessment include:
- Adverse event reports
- Audits
- Manufacturer/ Distributor/End User
- Public complaints
- Residue monitoring
- Decisions of international regulations

Keys: blue denotes HSNO process, green denotes ACVM process

Appendix 3: High-profile options considered but not recommended

This table provides an overview of notable options we explored but have not recommended. We have also provided underlying rationale for those decisions. This is not a comprehensive list of options considered but, instead, highlights ones we expect Ministers or stakeholders may have strong interest in.

Discarded option	Rationale
Single regulator and regulatory system (like APVMA in Australia) or single front door	Designing an approval path for agricultural and horticultural products within one regulatory system was initially considered during the development of the HSNO and ACVM Acts. However, considerations of effective risk management led to a decision to split it across the two regulatory systems. Over time, we have had well-developed, existing regulatory systems, and there are benefits to the current split system. Our analysis was that while redesigning to create a single regulatory system would have some marginal efficiency, transparency, and certainty benefits, this would be outweighed by the potentially significant costs and disruption that could occur to application processing in the medium-term while restructuring and legislative change occurred. There are also benefits to retaining specific expertise alongside related subject matter experts and to retaining current separation, specifically MPI's strong trade, primary production, biosecurity, and food safety focus and the strong domestic environmental considerations of MfE and the EPA. There is a risk that a single regulator would focus on or prioritise one area over another (for example, economic productivity versus environmental protection), which could generate perverse outcomes over time. This was the justification for the current regulatory split when the legislation was originally developed. The current system strikes a relatively sensible balance between the focus areas and helps protect against potential regulatory capture. Approximately 90% of applications processed by NZFS are variations to existing registrations, and 10% are to register new products. Some of these products will be authorised via group

	standards, or may be under the same individual approvals, suggesting that less than 10% of applications received by NZFS would also seek approval from the EPA. This significantly impacts the efficiency benefits that a single regulator or single front door can provide. Applicants are also often ready to apply to the EPA before they are ready to apply to NZFS. For this reason, we have not recommended moving to a single regulator and regulatory system at this time, as we consider the benefits are likely to be achieved in ways that would be less disruptive and more cost effective. We considered a single front door, as a lower cost approach. However, there would still be significant costs in developing a single front door. Given the small number of applications that are ready for both regulators at the exact same time, we do not think the benefits would outweigh the costs.
Automatically approving products based on the approval of two overseas regulators	We have recommended a streamlined assessment pathway for products approved by overseas regulators with a very limited scope and clear constraints for products not being used in the food supply. Other than the narrow constraints identified above, we consider that an automatic approval based on two overseas regulators' decisions would have unacceptable impacts on the effectiveness of risk management, in light of the very different production methods, use patterns and climate in New Zealand. This could have unacceptable trade implications, as overseas regulators would not conduct comparable trade risk evaluations. We consider regulators should be pragmatic and use information from international regulators as much as possible, as indicated in recommendation 8.
Agricultural and Horticultural Products Strategic Advisory Council (AHPSAC)	We considered an option of a strategic advisory council to improve transparency in the system, drive continuous improvement and efficiency, ensure strategic alignment across the regulatory systems, and improve stakeholder input into the approval path. AHPSAC would be made up of senior members of agencies and stakeholders with an independent Chair. AHPSAC would have a mandate to provide advice directly to Ministers, the Chief

	Executives of MPI and MfE, and the Board of the EPA, including on the implementation of these recommendations. We tested this option with the Sector Reference Group, who were strongly supportive, but noted the challenges in defining clear terms of reference, resourcing implications, and risks of real or perceived regulatory capture. Agencies saw value in engaging jointly with industry at the leadership level but expressed significant concerns with establishing a dedicated Council for this purpose, including administrative burden, managing potential conflicts of interest and regulatory capture, role of industry within the Council in developing and providing official advice to Ministers, and cost to implement and maintain. Our conclusion is that recommendations 1, 2 and 3 will be a more pragmatic and cost-effective approach to addressing the issues raised and will better manage the risks of regulatory or policy capture.
Removing or revising the 'precautionary approach' in section 7 of the HSNO Act.	Several stakeholders raised the precautionary approach (section 7 of the HSNO Act) and were of the view that this provision caused EPA to take a more risk averse approach to the approval of agricultural and horticultural products. The precautionary principle or approach (and the many variations of them) has been developed internationally as a means of avoiding danger to human health and the environment in situations where there is a high degree of uncertainty, and the effects of policy decisions are possibly irreversible. There is always a level of scientific uncertainty that must be managed. We consider section 7 of the HSNO Act was appropriately designed to require decision makers to "take into account the need for caution" as opposed to international constructions of "*the precautionary principle*", which requires precautionary action be taken where there is uncertainty. We do not consider section 7 significantly impacts on the risk tolerance of EPA. Therefore, we have not recommended amending or removing this section.
Amending the ACVM and HSNO Acts so that their	The stated purpose of the ACVM-HSNO regulatory system is to manage risk/adverse effects of products and substances. Some submitters suggested that the purpose of the respective acts

purpose is to enable the use of products rather than managing product risks	should be amended to 'enable the safe use', or to 'enable the use of greenhouse gas inhibitors'. We considered this, but our view is that the regulations exist to address concerns about the risks associated with agricultural and horticultural products. To do this, the regulators place restrictions on their supply and use. While it is appropriate that regulators consider the benefits of products, their primary purpose is to ensure that the restrictions put in place are cost-effective. It is not their function to enable the use of products. We have noted in Chapter 5 that there may be opportunities as part of longer-term regulatory stewardship to better define benefits and emphasise a least-cost approach to regulation.
Developing a group standard for research and development approvals	Some submitters suggested a group standard for research and development trials. The EPA has already undertaken significant efficiency work in response to concerns on the timeframes for research and development approvals, and there is now little to no queue for these assessments. We also note group standards were not designed for this sort of approval. Given this, we consider the resource required to develop group standards could be more efficiently and effectively used for developing group standards for products currently in the queue awaiting assessment. We do encourage the EPA to collaborate with industry on the design and development of group standards, and there may be value in considering group standards or other tools to support trial approval in the future. However, priority should be placed on reducing the queue of applications.

Appendix 4: Quantitative impact assessments

Improving access to agricultural and horticultural products

Scenario analysis of economic impacts

November 2024

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Summary

This analysis assessed the potential economic benefits of improving access to regulated agricultural and horticultural products in New Zealand, focusing on three scenarios examining the costs of regulatory delays and impeded access to new products.

Scenario 1: Delayed diffusion of innovation

- Faster access to new products, across all agricultural sectors, can lift primary sector productivity.
- Halving regulatory approval times could generate benefits of $272 million (present value) over 20 years.
- Annual benefits peak at $64 million after 15 years, equivalent to 0.4% of agricultural GDP.

Scenario 2: EU market access risk for fruit and vegetables

- New Zealand growers need access to new products to stay ahead of international standards for agricultural chemical use while maintaining product quality.
- We examine the potential impact of new regulations in the EU and value the risk of lost market access for NZ fruit and vegetable exports at $250 million (present value), if growers cannot access products needed to meet new standards.

Scenario 3: Deterring investment in novel methane inhibitors

- We use the case of a novel methane inhibitor to illustrate how regulatory delays affect companies' decisions to apply for approval/registration in New Zealand.
- Expediting approvals could deliver $43-183 million in benefits (present value) through earlier and lower cost emissions reductions
- Findings illustrate how regulatory delays can prevent products from reaching markets entirely, not just delay their arrival.

Not a cost-benefit analysis

Our scenarios are hypotheticals, intended to gauge the scale of benefits from regulatory improvements or, equivalently, the value at risk from the status quo.

We have not examined exactly how regulation or regulatory procedures would have to change to improve on the status quo nor the costs associated with change.

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1. Purpose and scope

We have been asked to assess the potential economic impacts of improved access to agricultural and horticultural products that are regulated by HSNO and ACVM.

The jumping off point is a cluster of issues raised in submissions to the Ministry for Regulation's Agricultural and Horticultural Products Regulatory Review:

- Fragmented regulatory system; duplication; lack of coordination.
- Regulatory system not responsive/adaptive to changes.
- Products not being processed fast enough; restricting access to products needed for optimum productivity.

1.1. Not a cost-benefit analysis

Our task is to scope the size of potential effects, using scenarios, without specifying exactly how regulation or regulatory procedures would have to change to achieve them.

That is, we are not modelling exactly what the Review will end up recommending, because that is not yet known.

Accordingly, this is not a cost-benefit analysis. Our assessment is about the size of the prize from three indicative examples of possible regulatory improvements or, equivalently, the value at risk from the status quo.

The results of the analysis must be read with the understanding that **we are not measuring net benefits of regulatory change**. A formal cost-benefit analysis of the full swathe of costs and benefits from the Review's recommendations is an important option for further research.

1.2. Focus on faster access and market value

We focus on the benefits of faster access to new products, as a short-hand for improved access. This is a convenient approach. It should not be read as an assumption that faster approval is always better approval; benefits of speed need to be balanced against risk and cost. But it is an appropriate approach in current circumstances where there are long queues for consideration of regulatory approval.

Our measures of benefits are, for the most part, measures of market value i.e. volumes of things produced with explicit prices in traded markets.

However, much of the purpose and benefits of regulation – of food safety and of environmental protection – is to safeguard non-market value. Given time, budget and information constraints, we do not estimate changes to these important non-market impacts.

1.3. High-level assessment based on what-ifs

Our analysis provides high-level estimates of benefits from faster access to agricultural and horticultural products. We take a lot of liberties by referring to regulated products, processes and users as if they are a single or a simple thing.

We are mindful that HSNO and ACVM regulate a complex system, from a risk perspective and an industry and product perspective.

In an ideal world, we would delve into more detail than we have. However, that has not been possible for reasons discussed in the next section.

1.4. Approach to scenario development

What we have done is to focus on measuring costs and risks from existing delays and hypothesise about reducing delays to infer benefits from regulatory change.

The scenarios we use to do this are presented in section 3 and the details of those scenarios are the subject of the rest of the report that follows.

In general, we have erred on the side of simplicity when constructing our scenarios. Our scenarios adopt baselines that, for the most part, assume a continuation of the recent past in terms of e.g. economic activity (levels), regulatory delay, and rate of application for new product approvals.

We have avoided speculating about the future size of agricultural industries and the downstream effects that improved productivity could have on overall national income or material living standards.

The reason we adopt this approach is that we want the link between our assumptions and our results to be as clear as possible.

Our analyses and results are scenarios – a series of what-if assessments. If we add to those what-ifs a series of other assumptions – such as the relative rate of growth of livestock agriculture versus fruit production versus forestry – we would only muddy the waters. It would be harder for readers to discern the extent to which our analysis reflects our assumptions around regulatory processes versus our assumptions about land use change and export demand growth.

This does mean that our analysis and results are apt, on balance, to err on the low side in terms of benefits from improved access to agricultural and horticultural products. We think that is appropriate under the circumstances.

2. Context

Prior research provides some examples about the value of agricultural and horticultural products. Some of this is very useful context. However, the evidence base for assessing the economic value of new products for New Zealand is patchy.

Industry studies illustrate overall economic significance

NZIER (2019) assessed the contribution of crop protection to New Zealand industry in 2018 was between $7.5 billion and $11.4 billion. KPMG (2021) assessed the contribution of animal health products in 2020 at $12 billion.

These economic contribution studies help illustrate that the economic value of these products is much greater than, say, the simple sum of their sales (although the same can be said for any products in any industry).

The economic contribution numbers in the NZIER and KPMG assessments are interesting, but they are an extreme account of the contribution of agricultural and horticultural products that are based on lost productivity if these products disappeared and were not replaced by anything else.

Our analysis differs in that it focusses more on what could be, rather than what is, and it looks at additional value from new products and uses, rather than the average value of existing products and uses.

Few studies estimate incremental importance of products

NZIER (2019) did also assess the economic impact of delays in regulatory approvals for new crop protection products. They hypothesise that the cost of a one-year delay could be between $7 million and $70 million (present valued sum over 10 years).[1]

Other examples of research that had similar objectives to ours are the analyses that were produced by NZIER (2020) and Sapere (Davies and Barton, 2021) on the value to horticultural producers of access to hydrogen cyanimide. Those studies considered the effects on yields and orchard incomes of having to use alternative products and methods to manage bud-break – i.e. the incremental value of those products.

Decisions have been made to continue to permit the use of hydrogen cyanimide products, for now. But this example provides concrete evidence of the reliance that some producers can have on a particular product and the losses they face if a product is phased out without a new product to replace it. The analysis in Davies and Barton (2021) suggests that hydrogen

[1] We are not entirely sure how this estimate compares to our assessments in this report. The basis for NZIER's numbers is not completely clear.

cyanimide has boosted kiwifruit output by around 10% annually, approximately $220 million in a single year, circa 2019.[2]

Overseas studies are more comprehensive

Overseas, there have been several studies of the effects of reducing reliance on pesticides and adopting alternative methods of pest control. Bremmer et al (2021) used case studies of several different crops in different EU countries to estimate the impacts on yields and incomes of reducing pesticide use in accordance with the Green Deal Targets. They found impacts that included a 0.3% yield reduction per percentage reduction in pesticide use for apples and a 0.4% yield reduction per percentage reduction in pesticide use for tomatoes.

A related analysis of the EU Farm to Fork Strategy, by Bremmer et al (2023), looked in detail at how greenhouse production in the Netherlands could adapt to the likely outcome of reduced access to crop protection products. The analysis catalogues the range of crop pests controlled with chemicals and assesses the prospects for continued access to those chemicals and alternatives. They do not *per se* estimate cost of reduced access to active ingredients but they do assess the risk to production and prices and suggest that costs of production will rise.

Decent NZ evidence on costs but not incremental benefits

There are few similarly detailed estimates for New Zealand that would allow us to estimate incremental economic effects of reduced access to existing products, risks of not being able to access replacement products or new and better products; and by extension the benefits of accessing replacement products or new products.

Studies of the costs of weeds, for example, illustrate that negative impacts on yields are potentially large ($1.7 billion in 2014 according to Saunders et al, 2017), crop- and climate-dependent, and apt to get bigger over time as resistance develops (Goldson et al, 2015; Hume, 2024) and weeds spread to new areas. But these studies do not venture to estimate the incremental net benefits of control[3] or new products that might more cost-effectively control these weeds relative to existing methods.

Similarly, Nimmo-Bell (2009, 2021) has collated a range of estimates of the costs of pest control, including expenditure on control, which is very useful context but does not assess incremental changes in costs over time or prospects for improvements in future. The latest estimate is that the cost of pests in 2020 was $9.2 billion.

[2] These are broad orders of magnitude comparing the central estimates in Davies and Barton (2021) with our estimates of kiwifruit gross output in March year 2020 ($1.83 billion). Davies and Barton (2021) are not entirely clear on the time period that their numbers relate to, but the latest year in their kiwifruit production data is for the 2019/2020 season.

[3] An exception to this observation is the case of bio-controls where there has been very useful estimates of the efficacy and economic benefits of pest control measures e.g. Fowler et al (2016,2024).

Long run returns to R&D suggest large benefits from new products

At a more general level, we know that R&D in agriculture very often delivers large benefits – with median social rates of return of 12% and many new methods and products producing returns that are multiples of that (Rao et al, 2020).

We cannot be sure that the successes of the past will repeat in the future. But these numbers do tell us not to be surprised by analysis that proposes large benefits from accelerating access to new products and processes.

Furthermore, the academic literature on returns to R&D in agriculture emphasises that benefits accrue gradually over time and are heavily influenced by the rate of adoption and efforts to promote adoption – or extension as it is referred to in agriculture.

Important pieces of the puzzle are missing

The above research provides some helpful information: the value of novel products (R&D), the costs that might be avoided with improved products, and the gains we have seen from existing products.

Unfortunately, they don't provide a sufficient basis for rigorous assessment of the potential size of benefits from changes to regulatory arrangements in New Zealand that might accelerate access to new agricultural and horticultural products.

Ideally we could assess the typical rate of arrival of new products or compounds by product type (herbicide, pesticide, vaccine etc) and use (ground crops, pipfruit, sheep etc) and the typical yield or growth improvements associated with such new products – including the extent to which new products replace existing products that are declining in effectiveness or need to be phased out for toxicity or risk-related reasons.

However, there is insufficient readily available information for us to follow that approach. And our time is far too short to collect such information from scratch.

Thus, we arrive at using three illustrative scenarios to assess the potential benefits of improved regulatory approval processes.

3. Scenarios

In conjunction with the Ministry for Regulation we have drawn up three indicative scenarios, described below. The three scenarios capture different aspects of the risks or costs imposed by impeded access to new products. We start with a very general scenario, and then move to more specific scenarios.

The first scenario considers costs of delay overall and on average across all industries and products. This is our most general scenario and assumes business as usual in all respects except changes to regulatory delays.

The second scenario addresses the possibility of a break in business as usual. It analyses the possibility of a serious shock to export demand for horticulture products – something that producers in New Zealand have been concerned about for some time.

The third scenario delves into a specific type of product – a novel methane inhibitor. This scenario principally assesses, by way of example, the effects of delays on companies deciding to join the regulatory queue altogether.

3.1. Overview of scenarios

Scenario 1: Delayed diffusion of innovation

We examine the effects of reducing regulatory approval times by half, for all products and industries.

The pipeline of new agrichemicals and animal health products helps to maintain productivity and promises improvements.

Slowing the rate of arrival of new products raises two slightly different risks

i. production or profitability decline from where they are now

ii. producers miss out on opportunities to boost production or profits.

Yields or production can go down, without new products, for reasons that include

- gradual loss of effectiveness due to e.g. pests or weeds developing resistance
- new product standards (private and public) that discourage the use of the products or mean paying a premium for alternative production technologies.

In this general scenario, we do not specify precisely which channels these benefits come through. Rather, we make a general assessment of the implied value in new applications and the benefits of bringing that value forward.

Scenario 2: Loss of horticultural market access to EU

We use the EU as a case study because the EU has a history of stringent domestic regulations of agricultural chemicals and is considering more stringent regulations in future which could spill over into equivalent requirements of New Zealand and others' exports to the EU.

An example of this is the EU maximum residue limits (MRL) for pesticides. These have been more stringent than in most other parts of the world and have included even more stringent requirements implemented by importers (private standards).

In the late 2000s, New Zealand pip fruit growers established a commercial advantage in selling to the EU by reducing pesticide residues (Kaye-Blake and Zuccollo, 2012).

There is some concern that this comparative advantage could be undermined by a combination of new regulations, private standards, and access to chemicals that can be used without increasing residues.

As we understand it, due to delays in approving new horticultural products, some horticulture producers are now limited to just one or two relatively 'toxic' pesticides that are accepted by EU regulators as being safe.

This presents a risk that these legacy chemicals could fall out of favour with EU regulators before new replacement ones are approved. Should this occur, New Zealand horticultural exporters could temporarily lose access to the important EU market.

In the extreme, a ban on some agricultural chemicals in the EU could mean a complete loss of access for exporters to the EU market, which makes up around 15% of fruit and vegetable exports from New Zealand.

We present scenarios for the effects of increased trade barriers into the EU for fruit and vegetables, due to new agrichemical use regulations in the EU and their application to imports.

We then weigh those effects against the likelihood of this occurring and present a result for the value at risk from reduced access to new products.

Scenario 3: Delayed access to novel methane inhibitors

We examine the effect of regulatory delays on the introduction of feed additives and similar products for reducing greenhouse gas emissions.

The search for cost-effective methods to reduce livestock methane emissions has been going on for many years. Arguably, the absence of such measures has impeded progress on reducing both agricultural emissions and New Zealand's mitigation efforts more generally.

Overseas, feed additives – referred to as methane inhibitors – have become available that have been shown to be effective at significantly reducing ruminant methane emissions. The cost of these additives is not prohibitive, and it appears they do not harm the animals or materially affect productivity.

There has, however, been limited uptake so far because of limited commercial or policy incentives to use them and because the products are relatively new. We acknowledge that these incentives could change over time should agricultural emissions pricing occur and/or overseas buyers/consumers start applying greater pressure on agricultural producers to show emissions reductions.

There are practical impediments to the use of methane inhibitors in New Zealand. The main one is that animals need to be dosed daily or more than once daily. For a large proportion of New Zealand livestock that isn't feasible, or at least the cost would be prohibitive (for now).

Another potential reason they are not available is that, for now, there is limited incentive for farmers to buy them if they were available and there is limited incentive for companies to make them available, seeing as the demand isn't there.

It is plausible that regulatory cost is one of the impediments that has prevented the breaking of that loop.

Companies that want to sell inhibitors in New Zealand face a potentially lengthy delay between applying to introduce the product and being able to sell their product and getting a critical mass of customers to start making a return on product development costs.

Even if a product has already been marketed in other countries, companies must invest upfront in developing the product for sale in New Zealand. This includes both commercial investigations and preparing materials for regulatory processes e.g.

- testing the efficacy of the product in New Zealand conditions (field trials)
- testing for residues of any active compounds in animal products e.g. milk
- gathering data on potential environment effects.

The cost of product development can be substantial. It is likely to vary significantly depending on the product formulation and whether it has been widely researched or used in other countries, but we understand from a small selection of industry case studies that a reasonable ball-park estimate is that it will fall in a range of $1 million to $4 million.

Delays in regulatory approvals can impact these sorts of investments in product development. A company that is considering an investment will judge its value on the expected returns it gets from day one. Each year without any return is a loss that will be counted against the investment.

The fact that demand[4] and regulatory approval are not guaranteed, means that companies will also require a premium to compensate them for risk.

[4] Demand risk in this case consists of policy-related risks, the risk that the product may not perform as expected in NZ conditions, as well as the more general problem that other suppliers might enter the market with new products.

Furthermore, the uptake of a new product is likely to be gradual. So even when the product is approved it may be some years before the company is making a reasonable rate of return.

Bringing these considerations together, it is easy to see that regulatory delay can be an important impediment to product development in New Zealand – potentially to the point of preventing it entirely.

Though this scenario focusses specifically on potential impediments to the sale of methane inhibitors, the logic applies more generally to any investment in developing new agricultural and horticultural products for the New Zealand market. Regulatory costs, including delay, can have visible and invisible effects, respectively:

- delaying benefits from new products undergoing approval
- preventing application for approval in the first place.

We measure the impacts of regulatory delay in terms of the market value of marginal reductions in greenhouse gas emissions.

3.2. Approach to quantifying the scenarios

We assess the three scenarios using bespoke simulation models accompanied by extensive sensitivity analysis. Bespoke models are necessary because each simulation is very different in nature in terms of product, industry and market coverage, precluding the use of a single generic modelling framework.

The simulation models are mainly static – extrapolating from existing conditions. The exception to this is where dynamics are indispensable to the question at hand: regulatory application and approval. In that case, we measure changes over time.

Our default evaluation period is 20 years, and, for simplicity, we assume that if regulation and regulatory approval processes were changed they would be changed at the beginning of 2025.

All values presented are in real terms (inflation adjusted). We also report present-valued benefits where lower weight is placed on benefits in the future, to account for greater societal concern about imminent impacts relative to impacts in the far future. For these weights we mostly use a discount rate of 8% per year as suggested by the Treasury for discounting commercial impacts. Where the benefits are considered part of long-term public benefits we use a 2% discount rate.[5]

We have not assessed wider economic impacts – beyond the sectors or situations we are analysing – in our scenarios. In principle, this means we are understating benefits. However, we are of the view that measuring downstream impacts would provide little additional insight, given that these are only scenarios, but would add a raft of additional assumptions and other complications.

[5] Treasury Circular 2024/15: Updated Public Sector Discount Rates for Cost Benefit Analysis.

4. Delayed diffusion of innovation

4.1. Simulation set-up

Revealed value in applications for regulatory approval

The fact that companies have applied for regulatory approvals tells us something about the value of those products.

For example, consider a company that is willing to invest $3 million in product development and regulatory approval. Conventional analysis of investment decisions suggests that expected returns are multiples of $3 million. That means the investing company expects a market need and a benefit to farmers and growers from buying their products that will return multiples of $3 million.

We examine the benefits of faster regulatory approvals by inferring the market value of new products from assumptions about product development costs inclusive of regulatory approval costs.

Further, we can calculate the effects of the new products on users (money value of yield improvement, loss avoidance or cost reduction) by assuming they are equal to the seller's benefits (return on investment).[6]

Assumptions required to run the simulations

The assumptions required to undertake this analysis are:

- product development costs[7]
- expected rate of uptake of new products
- investors' required rates of return
- investors' time horizon for evaluating the investment
- time taken to obtain regulatory approval[8]

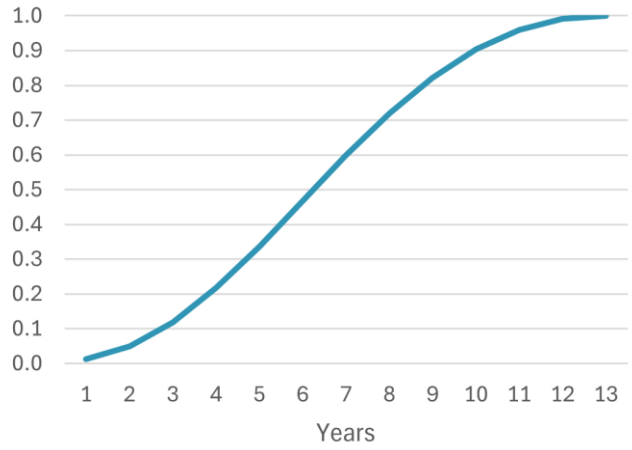
[6] We motivate this assumption three ways. First, buyers need a cost-benefit ratio that is greater than 1 before they can be persuaded to change to a new product. Second, benefits to users will vary. Some benefits will be very low and users will be very price sensitive. Others will have a very high willingness to pay e.g. because they have had a pest event and/or a rapid build-up of resistance on their property. So sellers trade off selling at a high price to some users versus selling to many users at a lower price. Third, it is conventional to assume, with no other information, that benefits are shared equally between producers and consumers.

[7] Includes regulatory approval costs but excludes costs of primary research and new overheads/capital expenditure. That is, for this analysis we assume that no new factories or labs need to be built – that all new products are either imported or produced with existing production facilities.

[8] This is the only time delay we include that will affect investment decisions. That is, for simplicity, we ignore the time path of product development expenditure other than regulatory costs.

- the number of applications being made for regulatory approval
- the time saving achievable for regulatory approvals.

FIGURE 1: ASSUMED RATE OF UPTAKE OF NEW PRODUCTS
Share of maximum market uptake/benefits of new products



Numbers used in the analysis

For all products we assume that

- the investment evaluation time horizon is 10 years[9]
- rate of uptake of new products follows the profile in Figure 1[10]
- regulatory approval times[11] can be halved
- the required rate of return is 15%.

Product development costs, time to obtain regulatory approval and required rates of return are assumed to increase by complexity of regulatory approval and extent of testing required for commercial development. As a starting point:

1) Products that contain novel active ingredients, are new to New Zealand and require **complex** regulatory approvals[12]

[9] This aligns with the standard time periods for data secrecy (so limits on competition) for novel products. Shorter payback periods might be used for new uses that do not receive 10 years of data protection, but rather receive a shortened 5 year data protection period. However we use a single 10 year period for project evaluation for simplicity.
[10] This is the time path of benefits from agricultural R&D, after new methods and products enter the market and up to the point where benefits typically peak, suggested by Alston et al (2011,2023).
[11] A halving of the time from first applying and joining a queue. Not the time taken to process an application once the processing is underway.
[12] Assumed to capture costs for ACVM applications in category A1 and EPA/HSNO category C.

a) $2 million for product development[13]

b) average of 5 years to obtain regulatory approval[14]

c) 6 applications are made per year, on average[15]

2) Products that are new to New Zealand, but do not contain novel active ingredients, and are **difficult** to scrutinise and prepare regulatory applications[16]

a) $1 million for product development

b) average of 23 months to obtain regulatory approval[17]

c) 7 applications are made per year on average[18]

3) for all **other** products[19]

a) $100,000 dollars for product development/approval

b) average of 5 months to obtain regulatory approval[20]

c) 140 applications are made per year.

[13] Approximate mid-point of a selection of case studies. The case studies are confidential but a public study by Kelly et al (2024) concurs.
[14] We assume that HSNO approvals are the key determinant of this value. This value reflects the Ministry of Regulation's assessment of current delays of 67 months, as at 30 September 2024, based on EPA data. We have rounded that figure down, because we understand increased resources are expected to reduce time taken to obtain approval. By rough comparison, the mean time to obtain approval for registration of ACVM category A1 products was between 200 and 300 days, on average in 2024 (2024 ACVM Workshop presentations (July)).
[15] Average annual volumes of A1 ACVM applications, past 3 years.
[16] Assumed to capture costs for ACVM applications in category A2 and EPA/HSNO categories A and B.
[17] Average of median wait times for approval of HSNO category A and B applications, weighted by the number of applications processed, in 2023.
[18] Average annual volumes of A2 ACVM applications, past 3 years.
[19] ACVM B1, B2 and new use (C4-C8) applications. Excluding research and R&D categories.
[20] Application-weighted average of wait times for approval for HSNO category A applications (only 8% of this category) and ACVM approvals in categories B1, B2, and C4 to C8 (average over agricultural chemicals and veterinary medicine applications).

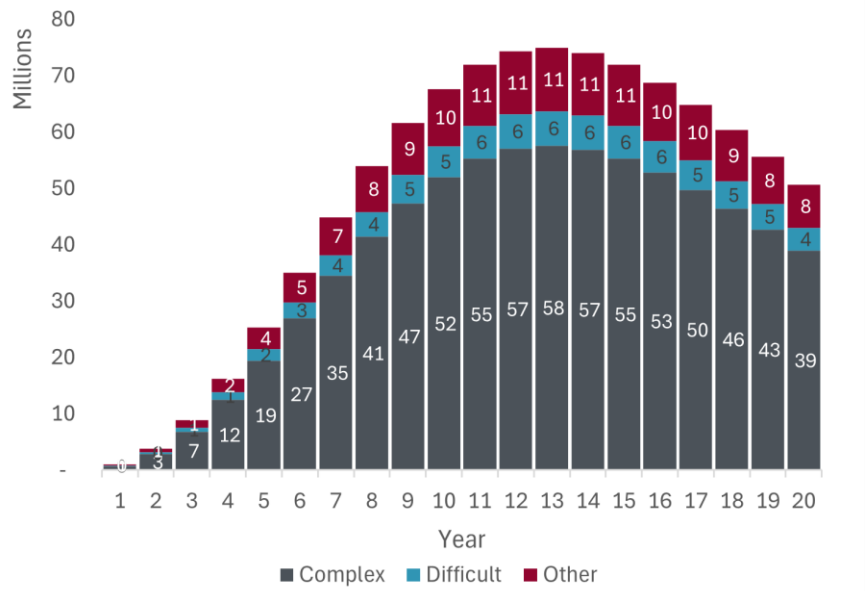
4.2. Baseline value of products in regulatory pipeline

Using these assumptions, we can estimate a benchmark market value of products submitted for regulatory approval, by backward engineering commercial break-even net cashflow (also user benefits) in the last year of the investment evaluation period and inferring cashflows in earlier periods using our assumed take-up rates and discount rates.

This produces a projected flow of value as shown in Figure 2. This is an estimate of the cumulative amount of new value in agricultural and horticultural products applying for approval in one year.

FIGURE 2: SIMULATED TIME PATH OF BENEFITS FROM 1 YEAR'S APPROVAL OF APPLICATIONS

Real millions of dollars. Not adjusted for timing of approval

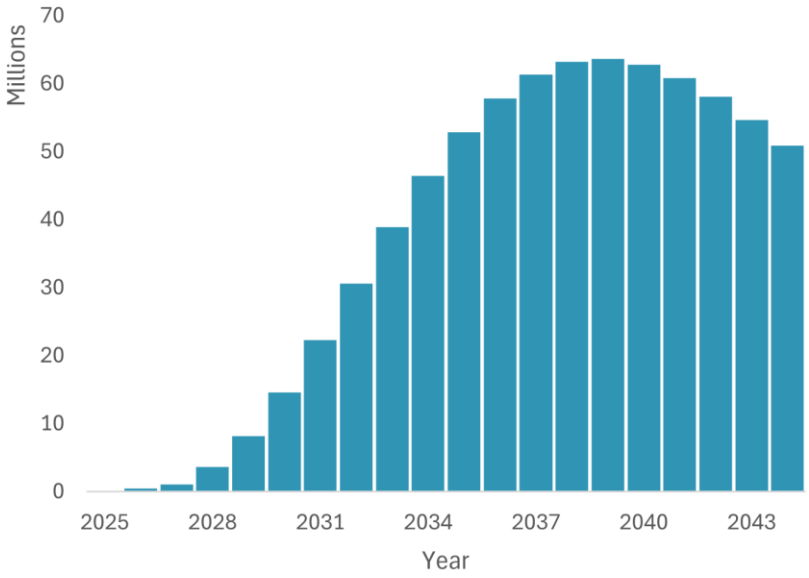


Each year new products come to market, and we assume they follow the same path in terms of timing of uptake and value for users stemming from one year of approvals, as shown in Figure 2. Combining 20 years' worth of approvals we get a net value for future use benefits – over and above costs paid for new products – that rises to $990 million in year 20, ignoring costs of delay. The total sum of value over the 20 years equates to a present valued net-benefit of $2.7 billion.

4.3. Benefits from reducing regulatory delay

Delays in regulatory approvals move this benefit stream forward in time. Assuming that approval times can be halved, the difference in timing of benefits yields a gain that is roughly equal to the use benefits of a single year's set of approvals (see Figure 3).

FIGURE 3: TIME PATH OF BENEFITS FROM BRINGING APPROVALS FORWARD BY A YEAR
Real millions of dollars, not discounted



On an annual basis the benefits peak at $64 million after 15 years and then trail off. That peak benefit equates to a **0.4% increase in agricultural GDP**.[21] This is, as it happens, equivalent to a little more than one year of agricultural GDP growth based on the average of the past 20 years.

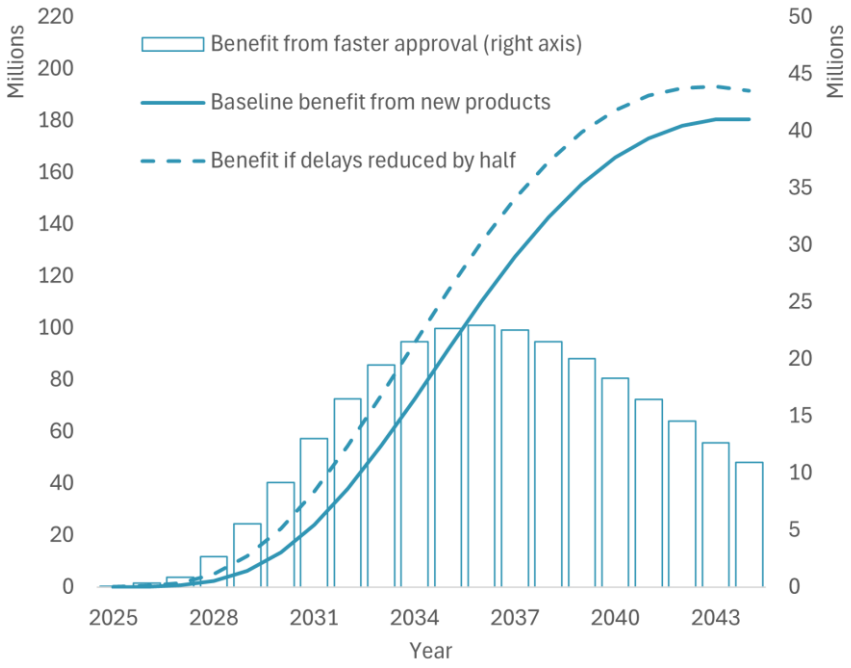
In present value terms (see Figure 4), the annual benefits peak in year 10 ($23 million) and **the sum of benefits over 20 years, discounted by 8%, is $272 million.**

In practice, delays could worsen without intervention. If that was taken into account, the benefits of addressing delays would keep increasing.

For the sake of clarity, recall that we do not consider here the resource costs of regulatory changes that might bring about a halving in approval times. As noted earlier, this report is not a cost-benefit analysis.

[21] This is based on extrapolating current price agriculture GDP in 2022 by the compound annual average rate of growth in constant price (real) GDP for the past 20 years.

FIGURE 4: BENEFITS OF HALVING REGULATORY DELAY, OVER 20 YEARS



5. Loss of horticultural market access

5.1. Estimating the size of potential trade effects

Quantifying the potential increase in trade barriers

To simulate the effects of EU market access barriers we need to assess the potential size of *de facto* trade barriers that could emerge.

A recent research article estimated that MRLs for pesticides have had a material effect on trade in fruit and vegetables (Hejazi et al, 2022). On average, trade declined by 8% when MRLs were 10% more stringent in an importing country compared to the exporting country.[22] This effect is equivalent to a tariff of 13%.[23]

Hejazi et al (2022) also find evidence for larger negative effects for trade into the EU, ostensibly because EU regulations are more stringent to begin with.[24] The effect sizes they find are equivalent to an approximate 20 percentage point tariff increase for a reduction of average MRLs in the EU in the order of 5-10%.

This provides a useful basis for gauging the scale of effects that agricultural chemical regulations can have on trade, beyond simply bans or other intractable barriers.[25] It points to rapidly increasing costs of trade with increasing regulatory stringency.

We use a 20% increase in trade costs as a starting point for our scenarios of possible and plausible impacts on trade if there is a change in regulation in the EU and insufficient capacity to respond to that quickly within New Zealand.

We have not linked this directly to changes in MRLs. MRLs are only one aspect of chemical regulations, and, in our view, there is good reason to believe that the estimates in Hejazi et al (2022) are likely to be capturing both MRL effects and other aspects of agrichemical import measures.[26]

Furthermore, our analysis is illustrative only. For example, we simulate the impact of a uniform percentage increase in trade costs for all countries exporting to the EU. This is a significant

[22] The measure of stringency used in the paper is highly non-linear – applying much higher weight to large differences than small differences. The measure is the exponential of the difference between exporting country MRL and importing country MRL as a percentage of importing country MRL.
[23] Assuming a trade elasticity of -6 for horticultural products (Fontagne et al, 2022).
[24] In the paper this is presented as impacts specific to trade between the EU and the US.
[25] This is important as a complete exclusion of trade is unlikely. Even very stringent regulation is unlikely to eliminate trade as some producers will be able to adapt to meet the regulations. For example, producers with very high productivity can wear the costs of adaptation, even if it means a reduction in their productivity.
[26] Also, it was impractical, in this assignment, to run sensible scenarios for changes in actual MRLs. It would have required making judgements about future changes in MRLs in all major exporting and importing markets.

simplification, albeit one chosen after considering whether the effects on New Zealand exporters would be likely to be smaller or larger than for exporters in other countries.

On the one hand, New Zealand may be at a greater disadvantage, relative to other countries, because small market size and a relatively slow approvals process means new products are likely to be slower to arrive here. On the other hand, New Zealand government and industry are better equipped than most to minimise the effects of new regulations. New Zealand's food safety systems, regulatory knowledge, diplomatic service and industry capability are very good compared to many other countries.

So, on balance, we simply assume a uniform shock to trade costs.

Simulating the impacts of cost increases

We simulate impacts of increased trade costs using data on fruit trade and vegetable trade for 163 countries in 2019.[27]

We use a large data set so that we can take account of the huge number of substitution possibilities that exist for exporters and importers if one market becomes harder to trade with. That is, as one market becomes harder to export to, alternative markets are found, albeit at a cost in terms of lower average export prices.

We estimate general equilibrium trade impacts using a model of changes in trade shares in response to changes in trade costs.[28]

This approach allows us to estimate impacts of increases in trade costs on trade flows and prices and incomes taking account of global adjustment in trade flows between all countries.[29]

A key assumption needed in the simulations is the degree of responsiveness of trade to changes in trade costs (the trade elasticity of substitution). Our starting point is a single value of -6, which is an estimate of the change in trade in response to changes in trade costs over long periods of time – years to decades – allowing for structural changes in supply chains and logistics.[30]

Our principal interest is in costs of adjustment over relatively short periods of time – 1 to 3 years. There is good evidence that trade elasticities are smaller (in absolute terms) in the shorter run (Boehm et al, 2020; Anderson and Yotov, 2020) – that trade adjusts more over the long run than in the short run. So, alongside the scenarios with a trade elasticity of -6 we

[27] This is the most recent large-scale dataset we have available that is not perturbed by COVID effects. Though it is a bit old, it still captures the key market shares in terms consumption and production and imports and exports.
[28] Presented in Head and Mayer (2014) and introduced by Dekle et al (2007)
[29] Hence the result is presented as a general equilibrium result – although only in respect of trade. It holds constant many aspects of the economy one would expect to change in a full general equilibrium model of trade.
[30] Average of product-specific trade elasticities for fruit and vegetables in Table 5 of Fontagne et al (2022).

examine effects on trade with an elasticity of -3.[31] Using both elasticities also helps to demonstrate the sensitivity of results to this key assumption.[32]

For simplicity, we conduct our simulations using aggregate trade for fruit and, separately, for vegetables; rather than simulations product-by-product. Implicitly, we assume no land use change or changes in investment and employment in these or other industries. We look only at trade and income changes.

We test for the effects of 3 different sized shocks to trade costs:

- 20% increase (low)
- 40% increase (medium)
- 80% increase (high).

Results of trade cost scenarios

The table below summarises the effects of increased trade costs on New Zealand exports of fruit and vegetables to the EU, New Zealand fruit and vegetable exports in total, and the gross income of the fruit and vegetable growing industries i.e. sales to domestic and international customers.

Trade cost changes of up 80% get close to an almost complete ban on exports to the EU. Of course, it does not require a ban to foreclose trade. Producers will move to other markets if trade becomes too costly.

In all scenarios the fall in the value of total exports from New Zealand is smaller (in dollars) than the reduction in exports to the EU, because of substitution to other markets (including an increase in sales volumes at home).

Shifting sales to other markets does come with a cost in terms of accepting lower prices. The impact on sector sales is thus a mixture of lower prices and lower volumes.

The **total effect of the simulated trade cost increase ranges from -$116 million for a 20% trade cost increase in the very short run, through to a cost of -$345 million for a more severe 80% trade cost increase that persists for several years**. Those are values for a single year in 2019 dollars. These costs are relative to total New Zealand exports of fruit ($270 million) and vegetables ($90 million) to the EU.

[31] Also, in our model we limit wage flexibility (so-called "sticky wages"), consistent with most models of shorter run adjustment. So, impacts fall most heavily on owners/profits.
[32] There are many competing estimates of trade elasticities and reason to believe some estimates are overstated (Simonovska and Waugh, 2014). A value of -3 aligns with long run results for recent estimates of elasticities of agricultural product trade from analysis of firm level data in Lashkaripour and Lugovskyy (2023).

TABLE 1: HYPOTHETICAL IMPACT ON THE FRUIT AND VEGETABLE SECTORS
2019 prices. Effects of increased trade costs due to changes in EU product regulations.

Trade elasticity	Trade cost increase	Sector	Value of exports to EU	Value of exports total	Change in sector sales (NZDm)
-6	20%	Fruit	-49%	-6%	-132
		Vegetables	-66%	-11%	-62
-6	40%	Fruit	-75%	-9%	-203
		Vegetables	-86%	-14%	-81
-6	80%	Fruit	-94%	-11%	-254
		Vegetables	-97%	-16%	-91
-3	20%	Fruit	-27%	-3%	-76
		Vegetables	-42%	-7%	-39
-3	40%	Fruit	-47%	-6%	-131
		Vegetables	-63%	-10%	-60
-3	80%	Fruit	-70%	-9%	-196
		Vegetables	-83%	-13%	-78

5.2. Implications for agrichemical regulation

The costs outlined in Table 1 provide a means of gauging the order of magnitude of costs that could be incurred if producers are not able to adopt products or practices that meet new market access regulations or demands of private standards.

Although the costs are hypothetical scenarios, they are matched by real world observations of the impacts of fruit and vegetable product regulations. For example, Hejazi et al (2022, p.2) say:

> *US exports of apples and pears to the European Union (EU) have declined by 80% and 97%, respectively, between 2008 and 2018 partially due to stringent residue limits revised by the EU in 2008.*

The question then is whether such costs could be avoided if local producers could access alternative methods of e.g. pest control and if they could, the extent to which delayed regulatory approvals could get in the way.

Simulation set-up

In the second part of this scenario we quantify the risk of substantial regulatory delays that prevent industry adjustments. To do this we assume:

- significant regulatory changes occur in the EU every 4 years, on average[33], and there is a one in two chance that new product regulations are put in place,[34]
- the new regulations have an equal chance of being equivalent to a 20%, 40% or 80% increase in trade costs
- regulatory delay means that New Zealand growers, who have been preparing for this eventuality, face reduced access to the EU market for a period of two years, on average but potentially for longer[35], while
- in a counterfactual scenario, we assume that market access is not impeded
- loss of market access will only happen once in 20 years – that learning from bad experience will ensure it only happens once.

Simulated value at risk

The chart below presents the simulated results of potential costs. The variation in cost size is a function of how large the trade cost shock is and how long it persists. In the extreme cases new products are several years to arrive and consequently the trade cost shock lasts several years. We see this as unlikely.

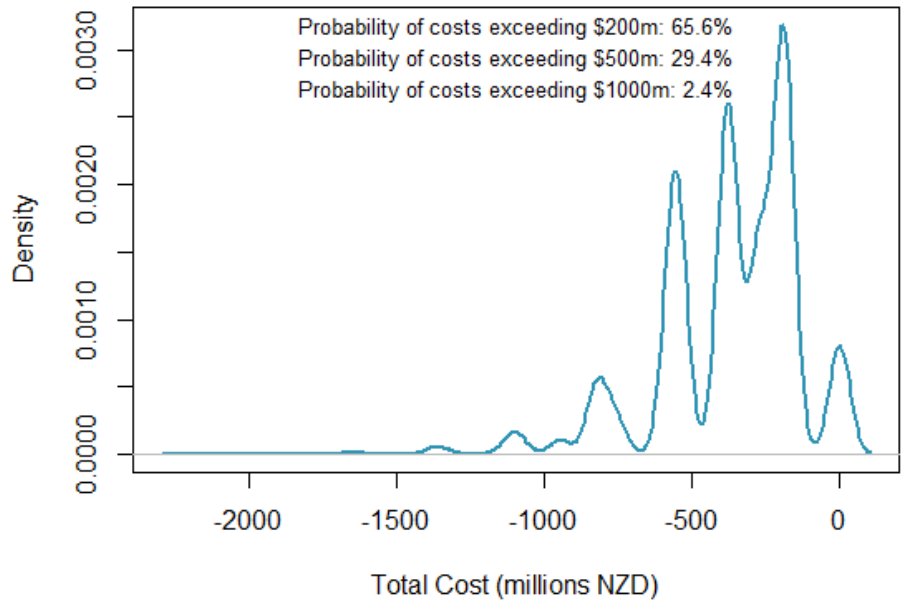
In the simulation the mean time for loss of reduced access is 22 months.

The most likely outcome, in this simulation, is that important potentially trade restricting regulatory changes do occur at least once in the next 20 years i.e. few simulations yield a potential net cost of 0.

Overall, **the mean probability weighted cost of not being able to respond to EU regulatory changes for horticultural chemicals is $375 million over 20 years (present value $250 million)**.

[33] This aligns with the frequency that EU common agricultural policies are reset. However, we assume that the event of regulatory change is random.
[34] We assume a 50:50 chance on the grounds that we have seen significant changes twice in the past ten years, albeit the latter changes (e.g. Farm to Fork strategy) look like they are being unwound before having an effect on trade barriers.
[35] We use a lognormal distribution (mean 0.5 and standard deviation 0.5) to capture uncertainty about length of the time period that market access is affected.

FIGURE 5: DISTRIBUTION OF SIMULATED COSTS



6. Delayed access to novel inhibitors

6.1. Simulation set-up and assumptions

We model the probability that a company would invest in developing a methane inhibitor for the New Zealand market, given expectations of the time taken for the product to be approved.

Given uncertainty about the cost-effectiveness of a novel inhibitor, we simulate the probability of market entry using a range of plausible values. Our base assumptions are

- product development costs are expected to be between $1 million and $4 million[36]
- companies require a rate of return between 12% and 20% annually[37]
- the product is marketed to dairy farmers only
- the unit cost of the inhibitor is between $50 and $150 per cow per year[38]
- the inhibitor is sold at a mark-up over unit cost that maximises profits, up to 50%[39]
- the inhibitor reduces methane emissions of treated cows by between 10% and 50%[40]
- product development work is expected to take 2 years, excluding the time taken for regulatory approvals.[41]

We model the potential uptake of the inhibitor by farmers using a version of the well-known S-curve of adoption of new products and technologies over time that includes adjustments for the faster uptake for more cost-effectiveness technologies (see Appendix for details).

The maximum market size for the product is uncertain given e.g. scope for competing methane mitigation technologies over time. We consider values of 500,000, 1 million, 2 million and 4 million mature cows, roughly equal to 10%, 20%, 40% and 80% of the current herd of mature dairy cows.

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[36] This is assumed to be inclusive of the cost of submitting and speaking to regulatory applications. We model uncertainty about development costs using log normal distribution (mean 14.5, standard deviation 0.3). This yields a range of roughly $1 million to $4 million. The central value in this range is $2 million, supported by an estimate from Kelly et al (2024).
[37] This range is informed by research on typical hurdle rates (Jagannathan et al, 2011; Melolinna et al, 2018; Edwards and Lane, 2021). We model uncertainty using a triangle distribution centred on 0.15.
[38] We start from numbers cited for Bovaer What Can We Really Expect from Elanco's New Bovaer®? | Dairy Herd and account for uncertainty about costs of novel inhibitor using a uniform distribution with costs that are +/-50%.
[39] The simulation accounts for price sensitivity of uptake, which limits the size of the mark-up.
[40] This reflects the potential reductions achieved with Bovaer in non-pasture environments with a range of, +/-20%. Some inhibitors have been shown to be even more effective than this but there are indications that this increased effectiveness can carry costs from lower animal weight. We model uncertainty about this number using a uniform distribution.
[41] Rounded down from 2.5 estimated in Kelly et al (2024).

Details around future climate policy and the size of farmer incentives to adopt the inhibitor are uncertain. We consider two possibilities. One is that incentives are linked to emissions prices that are expected to rise over time from $70 per CO_2 equivalent tonne of emissions to $270 per tonne. The other is that there is a fixed subsidy of $100 per cow that is expected to be constant over time.[42]

6.2. Benefits of reducing regulatory delay

We find that regulatory delays can impede market entry. Although they are a relatively minor consideration compared to expectations about policy and incentives and market size.

Figure 6 and Figure 7 illustrate. The first of the figures shows probability of market entry if the potential market is large (80% of the current herd). It shows that regulatory approval delays only impede market entry a little if uptake incentives are fixed and not at all when they are rising over time with emissions prices. If the market is large and pay offs from entry are growing over time, the cost of delay is not large enough to have much effect in terms of deterring market entry.

Figure 7 shows that with a much smaller market potential (10% of current herd), delay can have a significant effect on profitability and therefore market entry. But the size of the effect depends on whether incentives to buy the new product are rising over time or not.

The fixed incentive of $100 per cow is a stronger incentive for adopting the inhibitor in the short run. But this potential for encouraging early adoption also means market entry decisions are more sensitive to expectations about regulatory delays.

When incentive rates are fixed, adoption occurs at the same rate regardless of when the product enters the market. So, delays are costly. A regulatory delay of 4 years causes the probability of market entry (0.16) to fall by around 20 percentage points compared to a regulatory delay of 2 years (probability of market entry 0.38). When incentive rates are rising over time, delays are not quite so costly.

Benefits of reducing regulatory delay are a combination of social benefits from reducing the cost of emissions reductions, by increasing the probability of market entry, plus the gains from bringing net benefits of emissions reductions forward in time.

[42] At the low end, a 10% reduction in emissions per cow is an average of 231kg of CO_2e per year. This means a fixed incentive of $400 per tonne of CO_2e reduced. At the high end of effectiveness in our scenarios the incentive amounts to $87 per tonne of CO_2e. At the mid-point the incentive amounts to $144 per tonne.

FIGURE 6: PROBABILITY OF MARKET ENTRY, LARGE POTENTIAL MARKET

Assumed market potential is 4 million cows. Chart shows how probability of market entry changes depending on delays in regulatory approval.

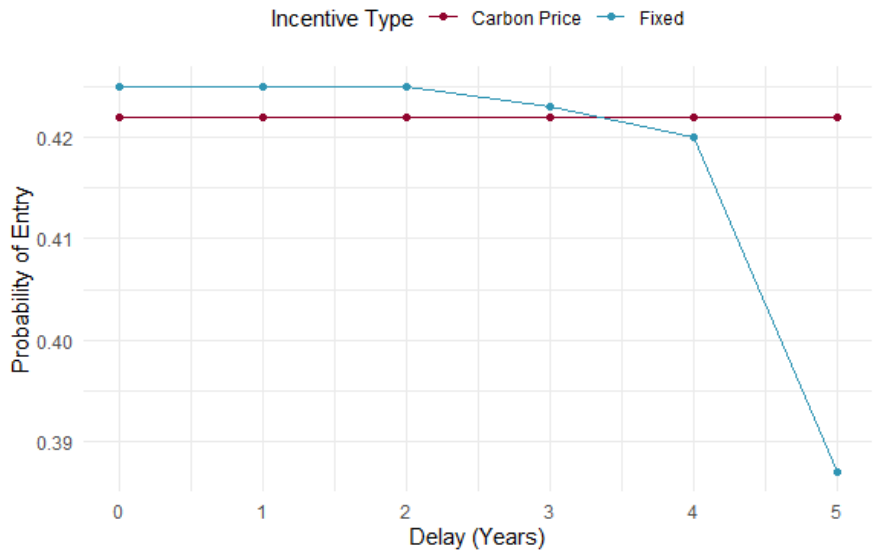
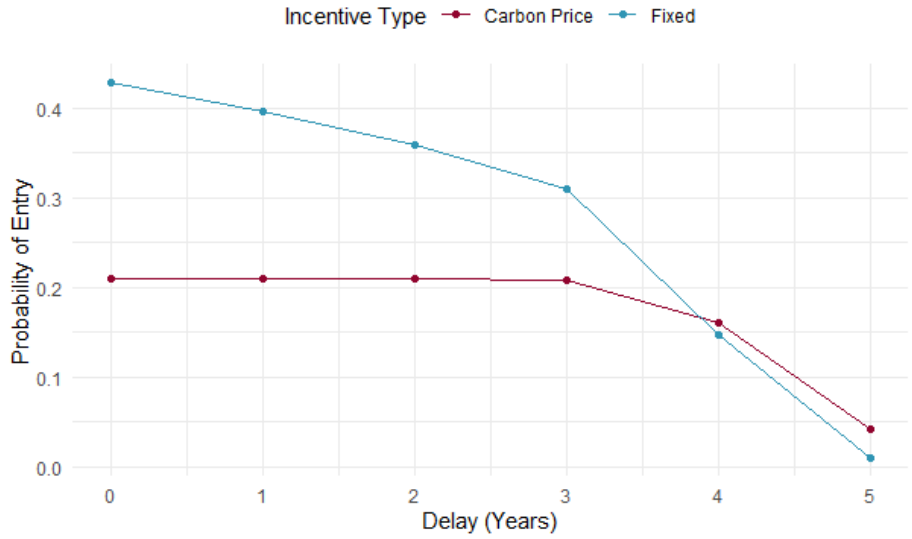


FIGURE 7: PROBABILITY OF MARKET ENTRY, SMALL POTENTIAL MARKET

Assumed market potential is 500,000 cows. Chart shows how probability of market entry changes depending on delays in regulatory approval.

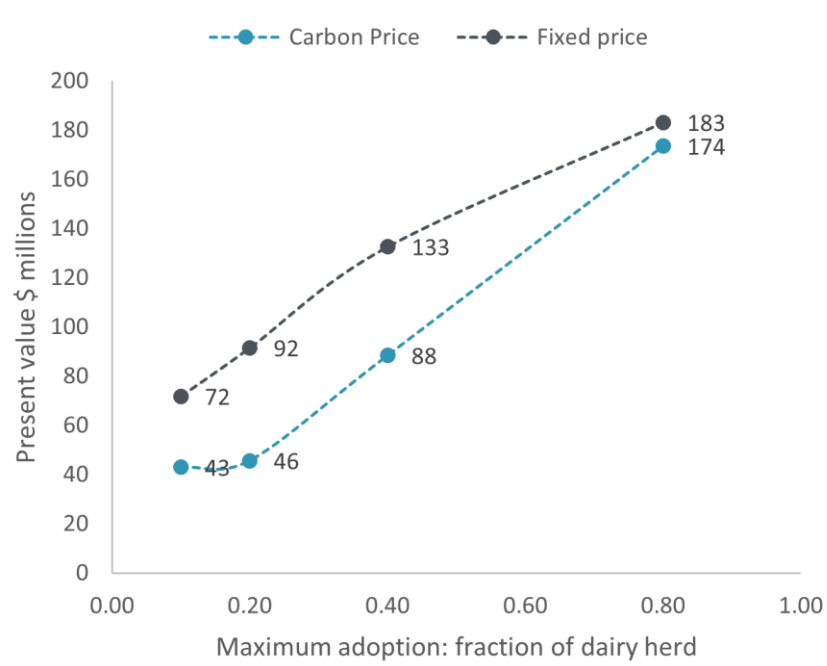


The **benefits of reducing regulatory delay range from $43 million (net present value) to $183 million**, depending on the potential maximum market penetration and policy incentive

used to encourage adoption. The range of results is presented in Figure 8. These are for a 2 year reduction in regulatory approval times from 4 years to 2 years.[43]

The benefits of expedited approvals have been valued using the expected reduction in methane emissions times the shadow cost of emissions proposed by the Treasury[44] less the incentive payment[45], in the case of the fixed price incentive, and less the payments made to the supplier in the case of the carbon price incentive. The benefits are then summarised as the present value sum over 20 years discounted at 2%.[46]

FIGURE 8: BENEFITS FROM EXPEDITED APPROVAL OF NOVEL INHIBITORS
Present valued benefit from change in cost of reducing emissions



Our estimates of benefits are only illustrative. We have not, for example, taken account of the effects of new cost-effective methane mitigations on policy, carbon budget settings, market demand, and hence emissions prices. We have also not allowed for actions that could be taken to accelerate adoption i.e. to catch up on the effects of delays.[47]

[43] We have used a slightly shorter baseline approval time of 4 years, compared to the 5 years used for complex approvals in scenario 1. This is on the grounds that a new cost-effective inhibitor is more likely to be expedited than other products due to potentially high public interest relative to many other agricultural and horticultural products.
[44] Table 1 in the Treasury guidance on Assessing climate change and environmental impacts in the CBAx tool - October 2024.
[45] Inclusive of a 20% uplift for deadweight loss of taxation.
[46] Public project discount rate recommended by NZ Treasury.
[47] Although such actions could be taken regardless of regulatory delays it is reasonable to expect that policy action/ambition will be a function of the level of agricultural emissions and a tightening carbon budget over time. That being so, a dynamic endogenous policy response could result in catch up.

Appendix: additional method details

Scenario 1: Effect of delays on diffusion

Assumed rates of uptake of new products

In scenario 1 we use a gamma lag function to approximate the lifecycle of new products from gradual adoption through to decline in effectiveness or replacement by better technologies.

Alston et al (2023) argue that this sort of function provides a useful approximation to what has been observed in markets for new agricultural products over many decades.

The function we use defines a set of weights over time (w_t) that describe how benefits of new products accrue and depreciate:

$$w_t = (t - g + 1)^{\frac{\delta}{1-\delta}} . \lambda^{t-g}$$

In our application the time variable (t) is integer years from product approval. The parameter g is years of gestation, which we set to 0 because we are focus on adoption.

We set the parameter values to $\lambda = 0.75$ and $\delta = 0.8$ selected to align with peak adoption and benefits occurring 13 years after commercial release. This aligns with observations in Alston et al (2023) of benefits peaking after 24 years from first investment and, within that time period, research and development times taking 10 to 15 years.

This uptake function is a simplification intended to capture average rates of uptake. In practice, some products take longer to penetrate such as new plant varieties that take time to grow and mature (e.g. vines). Other products such as pesticides might be taken up much more quickly if there is a pressing need for them.

Returns on investment in developing new products

We infer expected commercial returns on investing in a new product using the following equations.

The first is for the maximum net revenue (π_H) at the end of the investment evaluation period/horizon (H) inclusive of time taken to obtain approval (q), given a required rate of return (r), initial nominal investment in product development (D) and expected rate of uptake of product (u_t):

$$\pi_H = \frac{D(1+r)^q}{\sum_t^{H-q} u_t \left(\frac{1}{(1+r)^t}\right)}$$

This maximum net revenue is the value required to ensure the investment breaks even, conditional on the required rate of return.

The uptake value u_t is a function of the weights (w_t) described above with maximum time to full uptake adjusted for time taken to obtain approval:

$$u_t = \frac{w_t}{w_{T-q}}$$

The assumed time path of net revenue is then a function of the rate of uptake (assuming a constant average price over time in real terms):

$$\pi_t = \pi_H . u_t$$

User benefits as a function of investor net revenue

The benefits to users are assumed to be proportional to commercial net profit and persist beyond an investors time horizon. The consumer benefit horizon (T) is assumed to be 20 years to align with our horizon for assessing benefits from improved access to products.

$$b_t = \frac{w_t}{w_T}\theta\pi_H$$

Our default assumption is that user benefits are equal to supplier benefits, so $\theta = 1$.

The above equations are used to depict expected benefits from the average product, with parameters varying by complexity of regulatory approval (as described in the body of the report).

To assess the overall benefits (B_t) of multiple approvals we simply multiply the assessed benefits of a representative product (b_{it}) by the expected number of products submitted for approval (N_i), where i indexes category of complexity for regulatory approval i.e.

$$B_t = \sum_i b_{it} . N_{it}$$

That yields a profile of user benefits for a given years' worth of applications.

Combining multiple years of new products

To assess benefits of new products over 20 years we take the sequence of benefits from a single year of products over 20 years (i.e. B_t above) and, indexing each element in the sequence by j=1,2,... 20, we add them so that total benefits (T) from multiple years accumulate as in:

$$T_t = \sum_{j=1}^{t} B_j . N_{t-j+1}$$

Scenario 2: Loss of horticultural market access

Model of changes in trade as a function of changes in trade costs

The model we use to assess the effects of changes in trade costs is a simplified model that relates changes in trade shares ($\hat{s}_{ij}$) to changes in trade costs ($\hat{\tau}_{ij}$) and changes in factory or farm gate incomes/output ($\hat{Y}_i$) using two related equations founded in structural gravity

models. The indices i and j denote origins (sellers) and destinations (buyers). The trade share values denote the share of a destination's expenditure that is spent on products from a given origin. All change ($\widehat{\ }$) variables are ratios of new values to baseline values.

The first equation explains changes in trade shares as a function of changes in output, changes in trade costs, baseline/initial trade shares (s_{ij}) and trade elasticity of substitution (ϵ):

$$\hat{s}_{ij} = \frac{\left(\hat{Y}_i \hat{t}_{ij}\right)^{\epsilon}}{\sum_i s_{ij}\left(\hat{Y}_j \hat{t}_{ij}\right)^{\epsilon}}$$

The second equation, based on a market clearing, explains changes in the value of sellers' output/incomes in terms of initial (baseline) output (Y_i), changes in trade shares, initial trade shares, initial (baseline) destination expenditure (X_j) and changes in destination output ($\hat{Y}_j$).

$$\hat{Y}_i = \frac{1}{Y_i}\sum_j \hat{s}_{ij} s_{ij} \hat{Y}_j X_j$$

We simulate the effects of changes in trade costs by imposing a change in trade costs. We then iterate over changes trade shares and changes in incomes until we find a solution that satisfies both equations.

For further details and background around this approach to measuring the effects of trade costs see Head and Mayer (2014).

Scenario 3: Delayed access to a novel inhibitor

Model of the rate of adoption of the new technology

We assume a path of diffusion, or adoption, of the new technology from the time that the technology is ready to be used to the time that maximum uptake has been achieved. We apply a version of the Bass (1969, 2004) model which is a mathematical expression of the well-known S-curve of adoption of new products and technologies over time. The model is:

$$a_t = p(m - a_{t-1}) + q\left(\frac{a_{t-1}}{m}\right)(m - a_{t-1})\left(1 + e\frac{c}{I}\right) + a_{t-1}$$

Where adoption at a given point in time (a_t, fraction of the maximum market uptake) is a function of:

- the rate of uptake by innovators (p, a parameter controlling rate of acceleration of adoption)
- maximum uptake (m, fraction of the market, default = 0.99)
- the rate of uptake by imitators (m, default value 0.38)
- elasticity of uptake (e, default value 1) in response to changes in incentives
- incentives measured by the private cost benefit ratio of (c/I , default value 1).

This diffusion model has the effect of assuming that all projects' adoption rates follow an 'S-curve' to maximum uptake – growing slowly at first, then rising rapidly and then levelling off as adoption approaches its assumed maximum.

References

Alston, J.M., Andersen, M.A., James, J.S., Pardey, P.G., 2011. The Economic Returns to U.S. Public Agricultural Research. American Journal of Agricultural Economics 93, 1257–1277. https://doi.org/10.1093/ajae/aar044

Alston, J.M., Pardey, P.G., Serfas, D., Wang, S., 2023. Slow Magic: Agricultural Versus Industrial R&D Lag Models. Annual Review of Resource Economics 15. https://doi.org/10.1146/annurev-resource-111820-034312

Anderson, J.E., Yotov, Y.V., 2020. Short run gravity. Journal of International Economics 126, 103341. https://doi.org/10.1016/j.jinteco.2020.103341

Bass, F.M., 1969. A New Product Growth for Model Consumer Durables. Management Science 15, 215–227.

Bass, F.M., 2004. Comments on "A New Product Growth for Model Consumer Durables" The Bass Model. Management Science 50, 1833–1840. https://doi.org/10.1287/mnsc.1040.0300

Boehm, C.E., Levchenko, A.A., Pandalai-Nayar, N., 2020. The long and short (run) of trade elasticities, NBER Working Paper w27064, April 2022.

Bremmer, J., Gonzalez-Martinez, A., Jongeneel, R., Huiting, H., Stokkers, R., Ruijs, M., 2021. Impact assessment of EC 2030 Green Deal Targets for sustainable crop production (No. 2021–150). Wageningen Economic Research, Wageningen.

Bremmer, J., Meisner, A., Bregman, C., Splinter, G., Horsting, A., Salm, C. van der, 2023. Future pathways towards sustainable crop protection in greenhouse horticulture: Anticipating consequences of the Farm to Fork Strategy (Wageningen Economic Research Report No. 2023– 041). Wageningen Economic Research. https://doi.org/10.18174/590279

Davies, P., Barton, B., 2021. Economic assessment of hydrogen cyanamide use in New Zealand (Report for the Environmental Protection Authority). Sapere Research Group.

Dekle, R., Eaton, J., Kortum, S., 2007. Unbalanced Trade. American Economic Review 97, 351–355.

Edwards, H., Lane, K., 2021. Why Are Investment Hurdle Rates So Sticky? RBA Bulletin, December 2021, pp.12–20.

Fontagné, L., Guimbard, H., Orefice, G., 2022. Tariff-based product-level trade elasticities. Journal of International Economics 137, 103593. https://doi.org/10.1016/j.jinteco.2022.103593

Fowler, S., Gourlay, A., Hill, R., 2016. Biological control of ragwort in the New Zealand dairy sector: an ex-post economic analysis. New Zealand Journal of Agricultural Research 59, 1–11. https://doi.org/10.1080/00288233.2016.1170050

Fowler, S.V., Groenteman, R., Paynter, Q., 2024. The highs and the lows: a cost benefit analysis of classical weed biocontrol in New Zealand. BioControl 69, 253–267. https://doi.org/10.1007/s10526-023-10225-2

Goldson, S., Bourdôt, G., Brockerhoff, E., Byrom, A., Clout, M., McGlone, M., Nelson, W., Popay, A., Suckling, D., Templeton, M., 2015. New Zealand pest management: current and future challenges. Journal of the Royal Society of New Zealand 45, 31–58. https://doi.org/10.1080/03036758.2014.1000343

Head, K., Mayer, T., 2014. Gravity Equations: Workhorse,Toolkit, and Cookbook, in: Handbook of International Economics. Elsevier, pp. 131–195. https://doi.org/10.1016/B978-0-444-54314-1.00003-3

Hejazi, M., Grant, J.H., Peterson, E., 2022. Trade impact of maximum residue limits in fresh fruits and vegetables. Food Policy 106, 102203. https://doi.org/10.1016/j.foodpol.2021.102203

Hulme, P.E., 2024. Potential risks of future herbicide-resistant weeds in New Zealand revealed through machine learning. New Zealand Journal of Agricultural Research 67, 17–27. https://doi.org/10.1080/00288233.2023.2210288

Jagannathan, R., Meier, I., Tarhan, V., 2011. The Cross-Section of Hurdle Rates for Capital Budgeting: An Empirical Analysis of Survey Data. Working Paper Series. https://doi.org/10.3386/w16770

Kelly, R., Bethell, M., Body, I., Kelly, A., Kemshall, K., Jones, A., Wong, M., 2024. The Potential Use of Bromoform as a Methame Mitigating Technology in Aotearoa New Zealand Farm Systems (Report for the New Zealand Agricultural Greenhouse Gas Research Centre). BioPacific Partners.

KPMG, 2021. Assessing the value of the Animal Health Industry to New Zealand (Report for Agcarm).

Lashkaripour, A., Lugovskyy, V., 2023. Profits, Scale Economies, and the Gains from Trade and Industrial Policy. American Economic Review 113, 2759–2808. https://doi.org/10.1257/aer.20210419

Melolinna, M., Miller, H., Tatomir, S., 2018. Business Investment, Cost of Capital and Uncertainty in the United Kingdom Evidence from Firm-Level Analysis (Staff Working Paper No. 717), Bank of England Staff Working Paper. Bank of England, London.

Nimmo-Bell, 2009. Economic costs of pests to New Zealand (Technical Paper No. 2009/31), MAF Technical Paper. MAF Biosecurity New Zealand, Wellington.

Nimmo-Bell, 2021. Economic costs of pests to New Zealand (Technical Paper No. 2021/29), MPI Technical Paper. Ministry for Primary Industries, Wellington.

NZIER, 2019. The importance of Crop Protection Products for the New Zealand Economy (Report for Agcarm).

NZIER, 2020. Reassessment of substances with the active ingredient of hydrogen cyanamide: The costs and benefits of withdrawing hydrogen cyanamide from the New Zealand market (Report to New Zealand Kiwifruit Growers Incorporated). NZ Institute of Economic Research.

Rao, X., Hurley, T.M., Pardey, P.G., 2020. Recalibrating the reported returns to agricultural R&D: what if we all heeded Griliches? Australian Journal of Agricultural and Resource Economics 64, 977–1001. https://doi.org/10.1111/1467-8489.12388

Saunders, J., Greer, G., Bourdôt, G., Saunders, C., James, T., Rolando, C., Monge, J., Watt, M., 2017. The economic costs of weeds on productive land in New Zealand. International Journal of Agricultural Sustainability 15, 1–13. https://doi.org/10.1080/14735903.2017.1334179

Schneider, K., Barreiro-Hurle, J., Rodriguez-Cerezo, E., 2023. Pesticide reduction amidst food and feed security concerns in Europe. Nat Food 4, 746–750. https://doi.org/10.1038/s43016-023-00834-6

Simonovska, I., Waugh, M.E., 2014. The elasticity of trade: Estimates and evidence. Journal of International Economics 92, 34–50. https://doi.org/10.1016/j.jinteco.2013.10.001

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