Ministry for Regulation
Te Manatū Waeture

Agricultural and Horticultural Products Regulatory Review

Narrative summary report

February 2025

Contents

1. Executive summary

Agricultural and horticultural products, such as pesticides, veterinary medicines and environmental inhibitors, are important to protect and manage plants and animals in primary production.

In New Zealand, access to these products is managed by two regulatory systems under the Agricultural Compounds and Veterinary Medicines Act and the Hazardous Substances and New Organisms Act.

They are administered by the Ministry for Primary Industries (MPI) and the Ministry for the Environment and regulated by New Zealand Food Safety – an MPI business unit, and the Environmental Protection Authority – a Crown entity.

There have been concerns about timely access to these products and their uses, which triggered the Agricultural and Horticultural Products Regulatory Review.

The Ministry for Regulation undertook this Review from August to December 2024.

This Regulatory Review Report is the result of focused research, engagement with sector representatives and interested parties, public consultation and robust analysis to provide insights into the efficiency of the approval path managed by two regulatory systems.

New Zealand faces a competitive disadvantage in terms of accessing products, given its relatively small market, reliance on crops that are minor in international terms, different farming practices and remoteness from main manufacturing bases.

It is therefore crucial that the costs associated with our local approval path be at an absolute minimum.

This means regulators and policy agencies keeping abreast of global trends and the broader risk management economic system, including non-regulatory initiatives.

If New Zealand's systems do not evolve, our competitive disadvantage could worsen, thus jeopardising the goal of doubling sector exports by value over the next 10 years.

Overall, the Review found that the existing 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 products.

A range of issues were identified, including the uncertainty and timing of assessments, the lack of strategic direction, disproportionate and complex regulation, and concerns relating to regulators' resources, tools and engagement.

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

The Review recommended 16 changes that will, as a package, improve the proportionality, efficiency, transparency and certainty of the approval path.

Implementing these recommendations, together with other non-regulatory opportunities and work already underway by agencies, is expected to improve access to products and increase regulatory efficiency for the growth of primary industries.

This would generate benefits to:

- manufacturers and importers of agricultural and horticultural products;
- end-users of these products, particularly farmers and growers; and
- potentially the environments when innovative and 'softer' products are timely available to replace old, environmentally unfriendly products and a diverse range of products is available to manage biosecurity risks.

2. Overview of the review

The Review engaged widely and asked challenging questions about the current approval path, while working closely with agencies and regulators to understand the current state and develop recommendations for change.

The Agricultural and Horticultural Products Review (the Review) was launched on 1 August 2024 following Cabinet approval of its Terms of reference. The Review is led by the Ministry for Regulation with joint oversight by the Ministers for Regulation, Food Safety and the Environment.

Purpose and scope

The Review was initiated after farmers and growers raised concerns that the approval path for these products - while necessary for international trade and managing risks - was unduly restricting access to the tools they need to be successful. The Review focussed on making improvements to the current approval path, as well as considering broader economic issues, such as key market characteristics and the role of government.

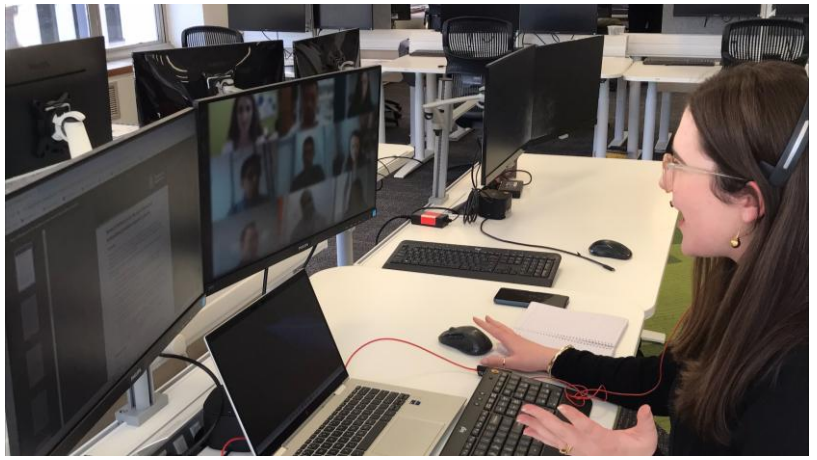
Engagement

The Ministry worked closely with core agencies (Ministry for Primary Industries (MPI), the Ministry for the Environment (MfE), New Zealand Food Safety (NZFS), and the Environmental Protection Authority (EPA)) throughout the Review. It was supported by a Sector Reference Group, which had membership from across product user groups, and a Senior Officials Advisory Group.

We used a range of engagement methods to gather information for the Review, including face to face and online meetings, to give those who wished to contribute to the Review ample opportunities to do so. The Ministry received more than 80 written submissions through its Engagement Hub and 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 organisations.

Analysis

Our analysis was informed by a combination of desktop research, engagement, and qualitative and quantitative methods. This included an economic analysis to confirm the market failures that warrant proportionate government intervention and a quantitative economic assessment of different scenarios concerning approval times and access to products. We undertook qualitative analysis of submissions and engagement feedback.



Developing our findings and recommendations

The findings and a range of recommendation options were tested with our Sector Reference Group, and their feedback was considered carefully. This was supplemented with bespoke targeted engagement on options with interested parties.

Findings and recommendations were tested with interested agencies and feedback from those officials has been incorporated where appropriate.

Our draft report was peer reviewed by international technical experts from Ireland and Australia.

3. Background

Background

Everyday farmers, growers and members of the public 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, we use products differently, have a distinct climate and environment, and are far from major manufacturing bases. These characteristics place New Zealand at a competitive disadvantage in terms of access to a diverse range of agricultural and horticultural products compared to its overseas competitors.

In New Zealand, the Hazardous Substances and New Organisms (HSNO) and Agricultural Compound and Veterinary Medicine (ACVM) regulatory systems manage product risks to human health, animal and plant health, the environment and trade interests and provide assurance for market access. The ACVM system is administered by MPI and regulated by NZFS, an MPI business unit. The HSNO system is administered by MfE and regulated by the EPA, a Crown entity. There are also non-regulatory initiatives to manage product risks.

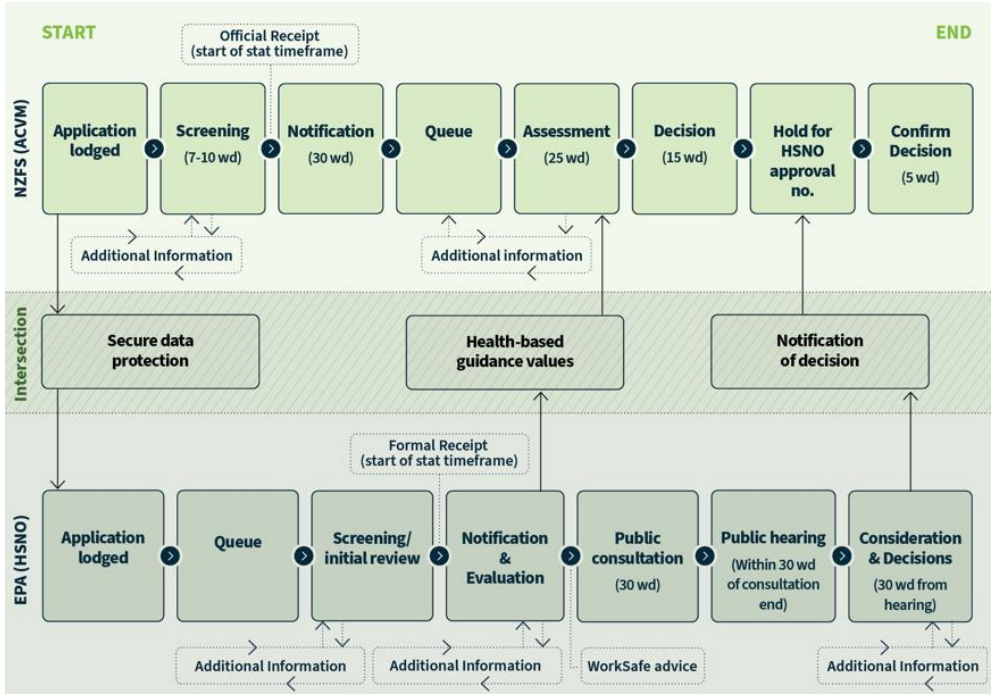
Products (in scope)

- Agricultural and horticultural chemicals (e.g., herbicides, fungicides)
- Veterinary medicines (e.g., antibiotics, vaccines)
- Vertebrate toxic agents
- Pet food and animal feed
- Environmental inhibitors
- Fertilizers

Key Statistics

- New Zealand’s market is small: in 2022, New Zealand accounted for 0.1% of global use/distribution of pesticides
- One of NZ’s major crops, apples, represents only 0.6% of global production, while apple production is one-tenth the size of maize production, the largest global production crop
- Products support NZ$43b in export revenue or 10% of New Zealand’s GDP
- Half of our export revenue is supported by these products
- New active ingredients can cost over NZ$460m to bring to market. This compares to NZ$2-4m for a new product with an existing active ingredient already approved elsewhere

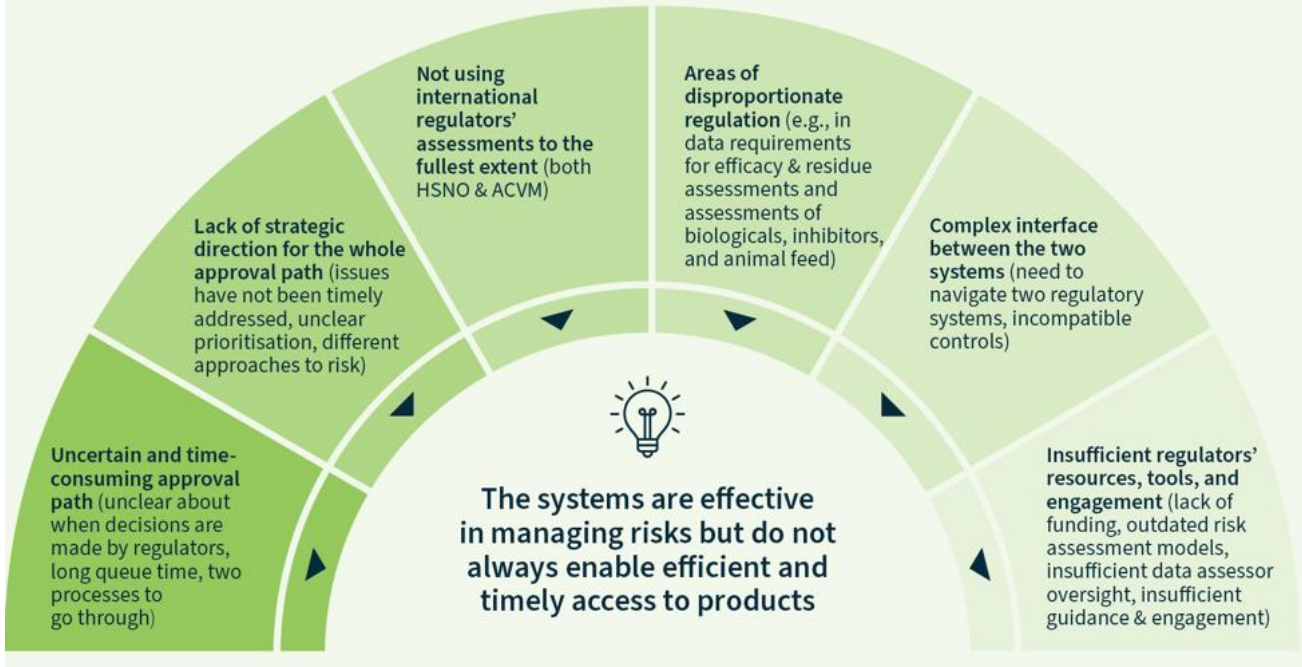
The diagram below describes a simplified flow diagram between the HSNO approval and ACVM registration process



4. Summary of findings and recommendations

The regulatory systems are effective in managing risks, including those to human, animal and plant health, trade, and the environment. However, we have identified a range of issues that need to be addressed if farmers and growers are to have efficient and timely access to agricultural and horticultural products.

Issues of the approval path for agricultural and horticultural products



The issues

The Review found the current approval path has not encouraged the introduction of new products and new uses of products to the local market, thus limiting options available for New Zealand users. We observed two regulators with very different approaches, and a break-down of trust and confidence between regulators and some regulated parties.

We have identified a range of issues relevant to:

- the speed and certainty of the approval path;
- the complex interface between the HSNO and ACVM systems;
- efficiency of the approval path and proportionality of regulation;
- regulators' resource, tools and engagement; and
- strategic approach for the approval path.

Separate economic analysis highlights several challenges for industry, end-users and regulators, such as changing consumer and trading partner expectations.

The recommendations

We propose 16 recommendations, which, as a package, will improve outcomes across the approval path.

5. Economic analysis

The Review's economic analysis highlights several challenges for industry, users and regulators. While there is a clear case for continued government involvement in risk management, regulators need to be open to how this is best achieved.

Economic analysis

- **Current global trends are affecting end-users' and regulators' actions, which could exacerbate New Zealand's competitive disadvantage.** Food standards are being increasingly driven by consumers, with their preferences regarding sustainability and climate change often going beyond regulatory requirements. This is resulting in older chemistry being replaced by "softer" products and biologicals. This trend, and the cost pressures faced by global manufacturers, who tend to direct investment and product supply toward major markets, could exacerbate New Zealand's competitive disadvantage.
- **The regulatory systems have a crucial role in managing risk**. While the influence of consumer choice and market forces is increasing, so too is the importance of regulation. The government has a continued role to play in addressing market failures, particularly environmental protection. The ACVM-HSNO approval path is also crucial for meeting the assurances provided by government that facilitate market access and benefit New Zealand exporters.
- **The global risk management ecosystem for agricultural and horticultural products will continue to evolve.** The New Zealand approval path is part of a broader system of regulatory and non-regulatory requirements that operate both locally and on an international level. It is essential that regulators take a forward-looking view to ensure the system they administer accounts for the key economic changes faced by industry and users.
- **New Zealand's regulators should continue to be pragmatic in managing product risks.** Regulation provides benefits to the community through reduced risks, and therefore harm. But it also imposes costs on industry, end users and others, through the restrictions it applies. The New Zealand systems already reflect the need to be pragmatic, with their provisions for self-assessment (for example, group standards and exemption from registration). It is important, however, that regulators continue to consider the trade-offs between the various risks they manage. If not, the approval path may not be effective in supporting the primary industry sector.

Independent economic modelling supports the case for change

The Review commissioned quantitative estimates on three scenarios to provide context for our recommendations

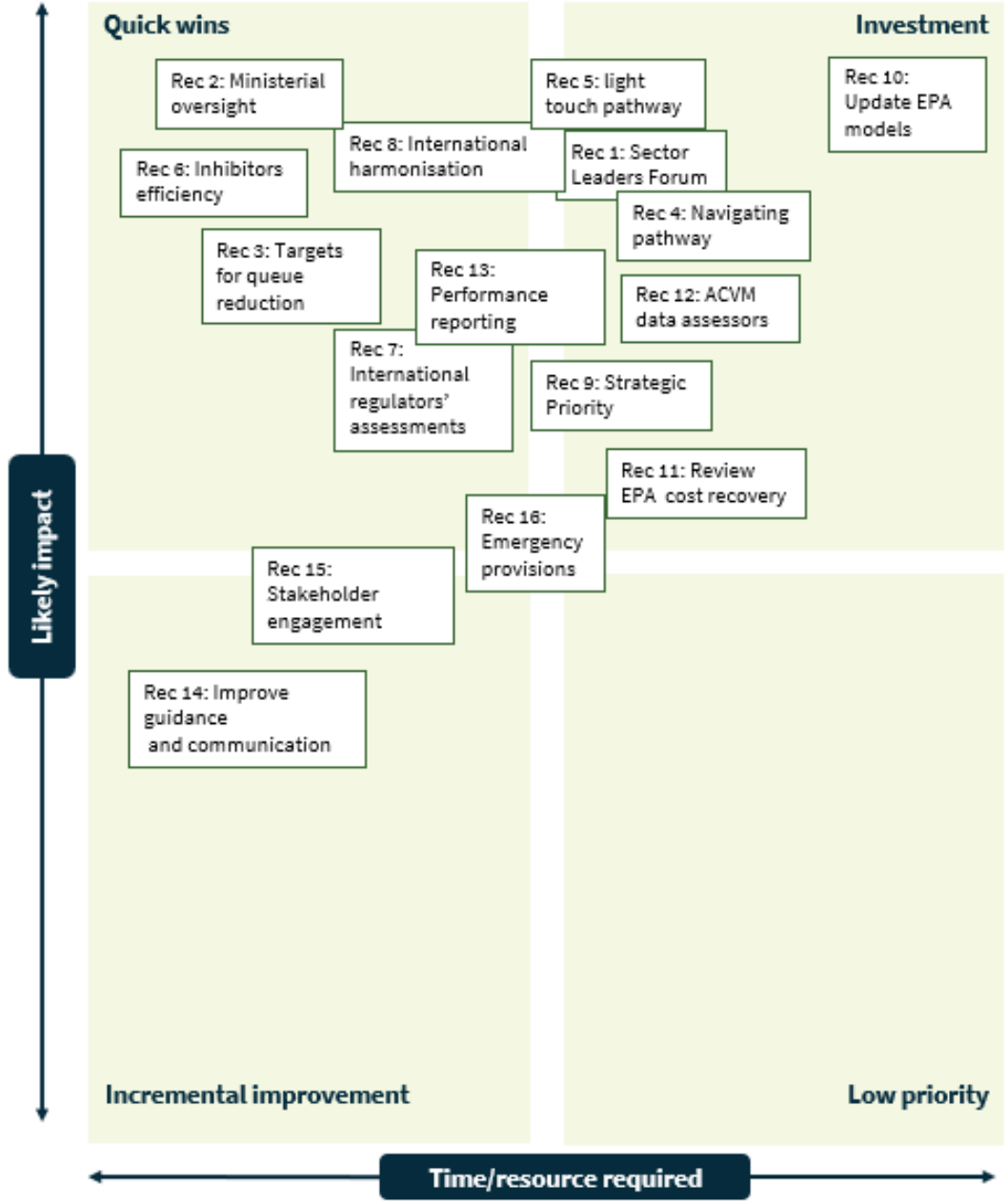
- Scenario 1 – reducing approval times by half equates to a present value benefit to users of **$272 million over 20 years**.
- Scenario 2 – more stringent regulations leading to New Zealand fruit and vegetable exporters having reduced access to European Union markets has the present value cost of **$250 million over 20 years**.
- Scenario 3 – reducing delays in the development of a new methane inhibitor has 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.

6. Impacts of the Review's recommendations vs the resources requirements for implementing them

This table provides a high-level assessment of the expected impact of our recommendations, and the complexity to implement. It helps to identify where recommendations are quick wins, and where significant investment is required to achieve them.

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

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



7. Specific issues and recommendations (1):

The current approval path is uncertain and time consuming with the primary concern being the HSNO queue.

The issues

There is no reporting on the total length of the approval path across the two regulatory systems. The Review has found it is not easy to estimate how long an application stays in the EPA queue or the total length of the approval path when a product requires both HSNO approval and ACVM registration, for example, new trade name product (TNP) with at least one new active ingredient.

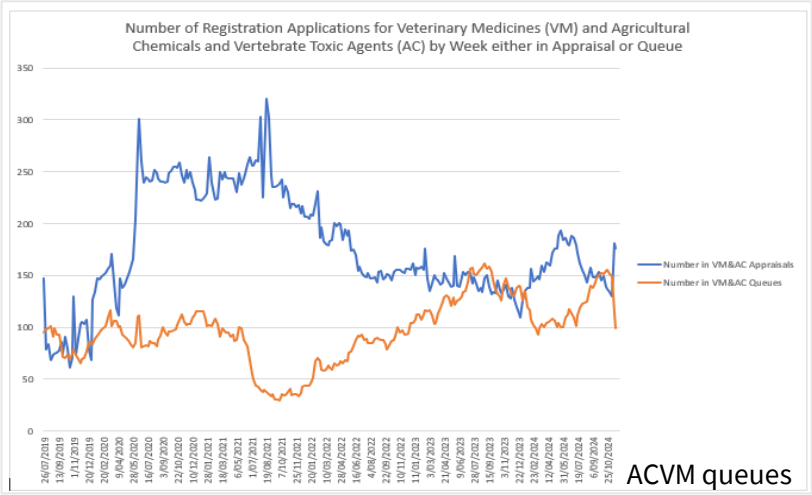
Statutory timeframes of assessment: up to 70 working days under the ACVM Act and 100 working days under the HSNO Act, depending on assessment pathways and excluding time waiting in the queues or where further information is requested.

ACVM and HSNO queues: Both the EPA and NZFS operate a "queue" for applications that have been submitted but have not yet started the assessment process. While the ACVM queue length fluctuated, the EPA queue rose steadily over the past four years, with a recent slight decrease in 2024. The median waiting time of the EPA queue was 31.6 months, while for NZFS the queue for novel product applications was 4.3 months.

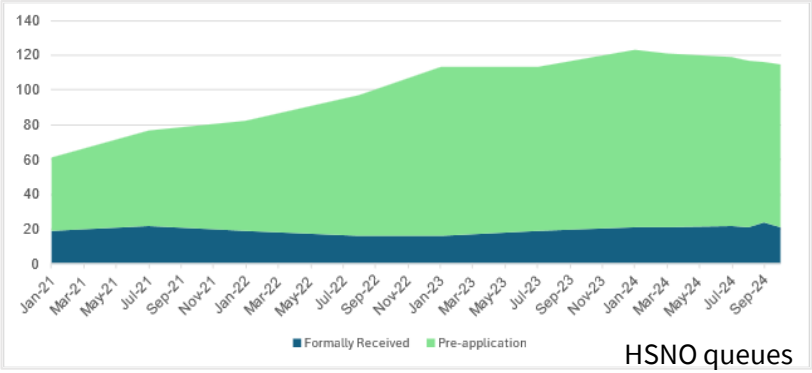
ACVM and HSNO processes: The median ACVM time for a new agrichemical TNP with a new active ingredient from 2022 to 2024 is around 32.1 months. For the most complex HSNO applications, the median application process has increased from 402 days (during 2013-2015) to 1,048 days (during 2021-2023). The EPA reports 75% of complex HSNO applications are currently processed within 36 months from formal receipt.

Together with the time in the queues, we estimate it would take **67.6 months (5.6 years)** to obtain both HSNO approval and ACVM registration if applications are filed in parallel now. If an applicant takes a sequential filing approach, the total end-to-end time could be around 99.7 months (8.3 years). This includes time in the queues and waiting for additional information from the applicant. In practice, it may be less as processing times improve.

During assessment processes, the clock can be stopped and restarted if additional information is required. These can be caused by an applicant's lack of due diligence, a lack of understanding and insufficient guidance from regulators during the pre-application process, or other reasons. This can make it harder to measure the performance of the regulators.



ACVM queues



HSNO queues

Recommendations

Recommendation 3 – Targets for queue reduction: responsible Ministers request targets to accelerate ACVM and HSNO assessments and reduce queues. Progressing other recommendations would help deliver on these targets.

7. Specific issues and recommendations (2):

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

The issues

- **The design of an approval path across the two regulatory systems** requires oversight to ensure the balance of effective risk management and timely access to products for economic growth. A clear strategic approach is important to support primary industries achieve their goal of doubling exports by value in 10 years. With the current lack of oversight and horizon-scanning, issues have arisen and not been addressed in a timely manner. If this continues, this limits the regulators' ability to ensure the approval path achieves the balance of managing risk, enabling commercial and innovative opportunities for growth, and minimising regulatory burden.
- **Differing views on risk appetite** are an inherent nature of regulatory systems managing risks – tension between different parties is to be expected and risk appetites can shift over time. Transparent engagement on what risk is acceptable is needed to ensure risk appetites remain appropriate.
- **Prioritisation** is key to ensure limited resources are used in the most impactful manner. Prioritisation should be considered with input from industry and other stakeholders at a senior level.

Recommendations

Recommendation 1 – Sector Leaders Forum: establishing this forum would enable improved engagement at the leadership levels between industry and regulators. This would provide shared Ministerial visibility and expectations over the approval path and upcoming challenges and ensure coordinated understanding of both the challenges the approval path faces and the roles that the sector and government can play.

Recommendation 2 – Ministerial oversight: Ministers can utilize available levers to ensure prompt implementation of this Review's recommendations and consider issues raised by the Sector Leaders Forum on an ongoing basis.

7. Specific issues and recommendations (3):

The complex interface between HSNO and ACVM systems have resulted in additional regulatory burden on industry and the primary sector.

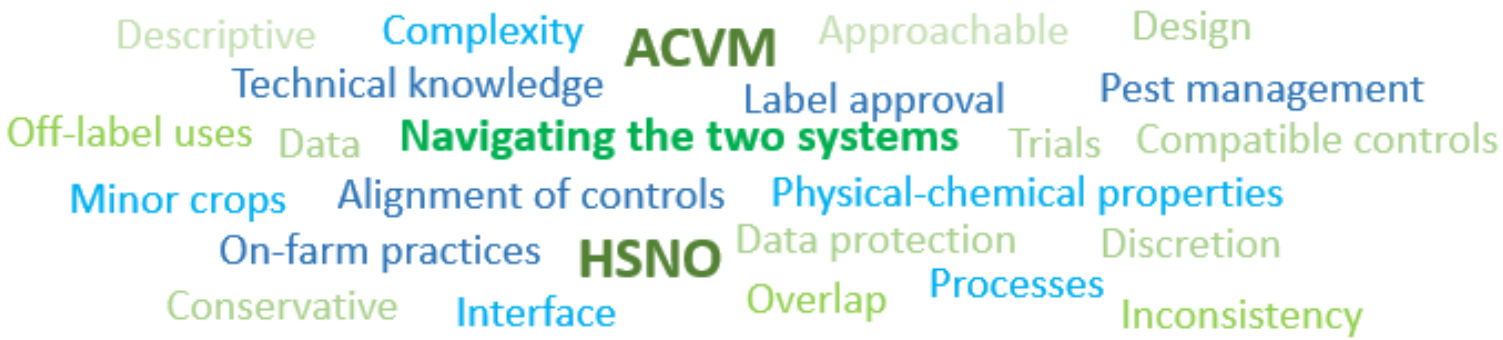
The issues

The approval path was intentionally split across two systems in the 1990s to promote 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, Parliament anticipated complexity and inefficiency which have been realised in practice.

Issues that have arisen include:

- complex navigation across the two regulatory systems with uncertainty around timing of decisions;
- 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
- sharing of industry knowledge and technical expertise.



Recommendations

- **Recommendation 4 – Navigating pathway:** make the two regulatory systems easier to navigate. Collaboration between agencies should happen at both operational and senior levels to consider opportunities such as alignment of controls, combined guidance, and streamlining data protection processes.

Non-regulatory opportunity to support growers of minor crops

- **Minor crops programmes:** we also note that other countries have implemented programmes that bring end users and manufacturers together and provide financial grants to support the generation of data needed to register products for minor crops. These programmes have been assessed as generating significant return on investment.

7. Specific issues and recommendations (4):

The approval path is not as efficient as it needs to be. Better use of overseas regulators' assessments and greater harmonisation represent key opportunities to make immediate improvements.

The issues

- **New Zealand is not using overseas regulators' assessments to the fullest extent:** New Zealand is usually not the first market for launching new agricultural and horticultural products, so there are opportunities to use information and assessments from recognised overseas regulators to support the assessment process. These opportunities have been considered and used by the EPA and NZFS but not to the fullest extent. We consider this is a critical solution to improve efficiency and streamline New Zealand's assessment processes, given New Zealand's small market and other competitive disadvantages.
- **International engagement can be further improved:** Both the EPA and NZFS have engaged at the international level to influence Maximum Residue Limits, adopt best practice, and harmonise requirements but there is room for more international engagement, especially around ACVM labelling.
- **Regulation of some products is disproportionate to the level of risks:** The two systems have already provided proportionate risk-based management approaches by introducing the group standards, rapid pathway, self-assessed variations and exemptions from registration. However, these tools have not been used to the fullest extent to ensure proportionality of regulation. We have found that regulation relevant to efficacy and residue assessment can be disproportionate for some products. Agencies are aware of the need for proportionate regulation and are making improvements in some respects.
- **Prioritisation** and the speed and certainty of the approval path discussed before are also efficiency concerns.

Recommendations

- **Recommendation 5 – Light touch pathways:** increase the use and better design of group standards, registration exemptions, and self-assessable changes.
- **Recommendation 6 – Inhibitors efficiency:** reduce ACVM efficacy requirements for inhibitors to the minimum required to manage risks.
- **Recommendation 7 – International regulator's assessments:** increase the reliance and use of assessments by international regulators while still considering aspects unique to New Zealand to improve efficiency.
- **Recommendation 8 – International harmonisation:** prioritise engagement at international level to support harmonisation of requirements and influence importing country Maximum Residue Limits.
- **Recommendation 9 – Strategic priority pathway:** explore a strategic priority pathway alongside the current first come, first served queue.

7. Specific issues and recommendations (5):

There are concerns relevant to regulators' resourcing, tools, and engagement.

The issues

- **Resourcing is affecting the current state of the approval pathway** with impacts on both systems but especially the size of the EPA queue. The EPA is 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 toxicological, ecotoxicological, and environmental fate models are outdated and no longer fit-for-purpose**. They may contribute to conservative controls or limitations on products and lengthen assessment timeframes if refinements are required. They also limit the ability to leverage information from international regulators as the outputs from the models may vary.
- **ACVM independent data assessor framework is not sufficiently robust:** ACVM independent data assessor process brings about benefits recognised by industry but oversight of this is insufficient resulting in quality issues and duplication.
- **The HSNO faster assessment** for products being approved in emergency situations has not been as well used as intended as it requires a responsible Minister to declare an emergency or special emergency.
- **Regulator engagement and communication** with applicants need to be improved to provide information on processing timeframes and reduce inefficiency. Appropriate forums are needed for industry to share knowledge and information for robust decision making. We have observed a "break-down of trust and confidence" between regulators and some regulated parties, including in the use of industry funding.

Recommendations

- **Recommendation 10 – The EPA models:** update the EPA's outdated risk assessment models and consider how to keep them up to date for the future.
- **Recommendation 11 – The EPA's cost recovery:** review HNSO cost recovery provisions and whether the level of cost recovery is appropriate.
- **Recommendation 12 – ACVM data assessors:** strengthen the framework overseeing independent data assessors to improve quality.
- **Recommendation 13 – Performance reporting:** prioritise improved performance reporting and review of the statutory timeframes.
- **Recommendation 14 – Guidance and communication:** prioritise the provision of up-to-date guidance, pre-application support, and provide transparency on application processing.
- **Recommendation 15 – Stakeholder engagement:** extend existing stakeholder engagement forums to operate across both regulatory systems.
- **Recommendation 16 – Emergency approvals:** review the emergency approval provisions under the HSNO Act, including better enabling products to be approved for biosecurity responses.

8. Next steps

- **the Minister for Regulation, Minister for the Environment, and Minister of Food Safety** will jointly consider the findings and recommendations to determine which recommendations to recommend Cabinet accept;
- **Cabinet** will consider what actions to invite responsible Ministers to progress, and any report backs that may be required; and
- **MPI (including NZFS), MfE, and the EPA** will respond to the directions and expectations of their Ministers by conducting robust policy and operational processes to support implementation.

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

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

9. Conclusion

Regulation plays a crucial role in maintaining food safety and a vibrant economy and society.

During this Review process we found issues in 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 resource for competing priorities and insufficient strategic direction to ensure regulatory efficiency are the fundamental causes of many issues raised, and that existing tools for efficiency and proportionality have not been used to their fullest extent.

We have recommended changes that will help alleviate identified issues and prevent future problems while not causing costly disruption to the design of the approval path.

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

While an approval path involving two regulatory systems will retain some complexity and New Zealand’s competitive disadvantage will continue to be an ongoing challenge, there are opportunities to support timely access to agricultural and horticultural products and continuing to effectively manage risks to human, animal and plant health, trade and the environment.