Agricultural and Horticultural Products Regulatory Review

Summary of Engagement

February | 2025

Ministry for Regulation
Te Manatū Waeture

Published in **February 2025** by the Ministry for Regulation, Wellington, New Zealand.

ISSN **978-0-473-73882-2** (Online)

This document is available on the Ministry for Regulation website: regulation.govt.nz

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Acknowledgement and privacy

The Ministry for Regulation (the Ministry) would like to express gratitude to all the stakeholders, experts and others who took the time and spent resources to make submissions or to meet with the Agricultural and Horticultural Products Regulatory Review team.

The Ministry has removed names and other identifying details from the information presented in this Summary of Engagement (this report). Where there was a small number of stakeholders in a particular category, we have been mindful to ensure comments cannot be attributable to a particular party.

If you have concerns with how submissions have been reflected, please contact us at: reviews@regulation.govt.nz.

Additionally, if you submitted and would like a copy of the personal information we hold about you, or want to correct that information, please make a Privacy Act request[1] in writing to: privacy.officer@regulation.govt.nz.

Engagement approach

The Terms of Reference (TOR) for the Review[2] set out the initial engagement approach. The Ministry engaged with industry representative groups and businesses through a mixture of online meetings and written submissions.[3]

Additional targeted engagement was held with stakeholders who could provide the Review with an understanding of the following areas:

- potential public health impacts;
- potential environmental impacts;
- considerations for the development of new products;
- the importance of appropriately managing product use to safeguard New Zealand's official assurances and trade for primary products; and
- cultural and other potential impacts to Māori.

Table 1 identifies the categories of stakeholders engaged during the Review. A list of groups and organisations who provided written submissions is attached as **Appendix 1**. The list does not include individuals.

[1] The Ministry of Regulation's guide to making Privacy Act requests can be found here.
[2] The Review's Terms of Reference can be found here.
[3] Approximately 60% of stakeholders who participated in direct engagement meetings also provided written submissions.

Table 1: Number of engagements by stakeholder category and engagement type

Stakeholder category	Number of engagements by engagement type	
	Direct (meeting)	Indirect (submission)
Agricultural associations (including peak bodies)	7	9
Horticultural associations (including peak bodies)	12	8
Product manufacturers (including representative associations)	5	19
Primary products exporters	2	3
Māori interests	3	2
Environmental interest groups	5	7
Public health	3	1
Research and development (R&D) companies and bodies	9	7
Veterinary associations	1	2
Growers	0	5
Government subject matter experts	10	0
Other (including individuals, local government, academics and researchers, consumers)	0	27
Total	**57**	**88**

Executive summary

On 1 August 2024, the Ministry for Regulation (the Ministry) commenced a review into the approval path for agricultural and horticultural products used to manage plants and animals under the Agricultural Compound and Veterinary Medicines (ACVM) and Hazardous Substances and New Organisms (HSNO) regulatory systems (the Review). The purpose of the Review was to assess how the current regulatory approach is delivering on and balancing the objectives of enabling access to products and ensuring that risks of products are known and appropriately managed. This report summarises what was heard from stakeholders during initial engagement.

Key themes

While stakeholders largely agreed that change was needed, they had different views on what those changes should be.

- Most acknowledged that the existing regulatory system effectively manages key risks, including risks to human health and to New Zealand's trade reputation.
- Most agreed that system changes should focus on ensuring the right balance between managing trade risks, minimising environmental harm, and ensuring those who grow and produce agricultural products and provide care to animals have access to the products they need.
- Most commented on the regulators' risk settings but expressed different views on how risks should be weighted and the level of scrutiny applied.
- Many agreed that the regulatory system, in its current form, has not kept up with the pace of change. They said that the systems must be managed in accordance with national and international environmental obligations and best practices, comply with free trade agreements, and align with international trends.
- Many described challenges from New Zealand having a two-regulator system. Although the regulators, New Zealand Food Safety (NZFS) and the Environmental Protection Authority (EPA), have separate and distinct responsibilities owing to their specific legislation, stakeholders who seek product approvals indicated that, from their perspective, there is unnecessary duplication in the end-to-end process. They noted New Zealand's system is particularly frustrating to those accustomed to overseas, single-regulator systems.
- Most mentioned challenges specific to New Zealand. Challenges they identified included unique climate and weather patterns, farming methodologies, and the need to protect native flora and fauna. New Zealand's major crops, such as kiwifruit and apples, are minor crops globally and manufacturers have less incentive to generate data and develop products for those crops than for staple crops like maize and wheat.

Opposing views

There were opposing views on some themes:

- Nearly all expressed views on how the regulators manage risks and what risks they should consider when making decisions. Views tended to be weighted towards each stakeholder's own interests.
- Views varied on the acceptable level of risk of agricultural and horticultural products.
- Some acknowledged the issue of "freeriders", which is when a regulator uses data that was produced by a different applicant to make decisions on a new application. Some acknowledged that the practice may broadly benefit the industry by facilitating approval of new applications. Others said the practice was unfair to those who

bore the costs of producing the original data.

- Stakeholders who export agricultural and horticultural products had different views (among each other) on regulator performance. They generally agreed NZFS appears to take a more risk-based approach than the EPA.
- How stakeholders defined "environment" and the effect of the definition on the regulatory system was different. Some expressed the view that the regulations should only focus on the natural environment while others said they should include the economic success of local communities.
- Stakeholders were divided on whether non-regulatory quality systems are robust enough to adequately manage product risks.
- Stakeholders did not agree on the level of prescription/flexibility that should be present in legislation.
- A few stakeholders said they were well supported by the regulators and experienced good communication from them during the application process. Many did not.
- Most stakeholders said that the approval process for new products takes too long, but one stakeholder countered this view, saying some industry expectations may be unrealistic.

Out of scope issues

Some stakeholders commented on matters that were out of scope of the review. For completeness, we have included those comments in this report, and they may be considered for possible future work on these regulatory systems.

In summary

Submissions and direct engagements reflected a variety of views including some areas of strong agreement and others where there was disagreement. While there was consensus that changes are needed to the regulatory system, submitters had different views about what those changes should be.

1. What does the current system do well?

Stakeholders acknowledged that the system effectively manages key risks

Stakeholders broadly acknowledged that the regulatory system is effective at managing key risks, including to human health and to New Zealand's trade reputation. Agricultural and horticultural stakeholders agreed that robust standards are needed for a good regime to protect trade, market access, public safety, and New Zealand's brand. Other stakeholders noted that the regulatory approval process gives users confidence that a product is expected to perform to an agreed standard.

Stakeholders told us some things the ACVM framework gets right

One manufacturer praised NZFS for having excellent communication with them while processing their application. Agricultural stakeholders also acknowledged support from NZFS during emergency/exotic disease incursions and noted that NZFS' processing times have improved in some areas in recent years.

A few stakeholders mentioned that the ACVM regulations were well-aligned with those overseas and acknowledged that New Zealand's regulatory focus on residues in exports was understandable given New Zealand's economic focus on agricultural exports.

One stakeholder mentioned that, from a crop protection perspective, the ACVM system works well. They noted that NZFS staff are solution-oriented, and it is clear to them that decision-making is driven by improving productivity and ensuring food safety. They acknowledged that as an applicant they always want decisions faster, but they are under the impression that NZFS are working as quickly as they can, considering their funding levels. Another praised the recently established Inhibitor Operational Forum, a stakeholder group.

Stakeholders praised the external/independent data assessment model, noting that it allowed NZFS to complete their assessments within statutory timeframes. One stakeholder considered it should be extended to help with applications under HSNO.

Stakeholders told us some things the HSNO framework gets right

One stakeholder noted that group standards under the HSNO regulatory system are effective, and they help to reduce the burden on manufacturers and importers. Several stakeholders noted that they would like the group standards to be extended to ACVM or used in different ways, further demonstrating general support for that regulatory approach.

One stakeholder also commented positively on the EPA's effort and initiatives to implement shorter application pathways.

2. What are the opportunities for improvement?

Some risk settings are not quite right

Regulator risk settings and decision-making

Most stakeholders commented on the risk settings of one or both regulators. Manufacturers, researchers, growers, and agricultural and horticultural associations generally indicated that the risk approach was overly restrictive or was not aligned to support trade.

Some producers and exporters said they do not support an overall reduction in risk management. Public health stakeholders noted that smaller Pacific nations rely on New Zealand's product approvals, which they said increases the responsibility for New Zealand to make good decisions.

Regulators' risk appetite

Stakeholders had different views on where responsibility for setting risk appetite should sit within the regulators' organisations, who should set it, and what factors should affect the settings. In general, industry stakeholders said the current system appears to be overly cautious. Environmental and public health stakeholders were comfortable with a cautious approach.

Risk appetites are not aligned between the regulators or among individual assessors

A few manufacturers discussed inconsistencies in risk appetite among external ACVM data assessors and between the two regulators. One commented that, because the legislation is not prescriptive, it is open to interpretation by assessors. They commented that there are different

things allowed/not allowed between the two regulators.

The regulators' risk appetites appear unpredictable and inconsistent

One industry stakeholder said that the regulators either do not have guidance or do not always follow their own published guidance. They perceive the regulators' approach as overly subjective or uncertain. This means applicants cannot predict how the regulators will assess the risk of their product.

Exporters also noted that the regulators' risk appetites appear to have changed over time.

The "precautionary approach" is misunderstood or misapplied for HSNO assessments

Many industry stakeholders expressed the view that the EPA is overly cautious and spoke broadly about how the "precautionary approach" in HSNO was misused. A few environmental stakeholders stressed the importance of the precautionary principle as a key factor in alleviating risks where there is uncertainty about adverse effects.

The level of scrutiny applied is not always proportional to the level of risk

Stakeholders had different views on product risk to trade or environment and the appropriate level of scrutiny new products should receive. R&D bodies, agricultural and horticultural associations, and manufacturers said that the risk settings weigh trade risk inappropriately. They did not have a unified view on what the appropriate weighting should be.

A few stakeholders, including some agricultural associations, said the trade risk cannot be understated and valued continued support for the regulator's ability to manage these risks. A few stakeholders made a distinction between risk management and risk avoidance, suggesting that the regulators tended towards the latter.

Environmental, manufacturing, R&D, public health, agricultural and horticultural associations all had similar comments on achieving what they thought was the right balance between the demand for innovation and economic return vs the risk to the environment and trade. R&D and horticultural associations noted that the same HSNO controls are applied to all products regardless of whether a particular product may pose lower risk.

There is no risk-based framework for low-risk products or products of similar risk

Manufacturers, R&D groups, agricultural associations, and others commented that the regulatory approach does not work well for low-risk products, or products with a similar risk to others which are already approved. They noted this results in disproportionate risk assessments. For example, stakeholders mentioned animal feed, for both companion and agricultural animals, as a low-risk product that is treated with a high-risk approach.

NZ regulators have a bespoke approach to managing risks

Several agricultural and horticultural associations, veterinary associations, and manufacturers commented on the New Zealand regulators' bespoke approach. They made international comparisons to how our regulators assess product risks. Environmental stakeholders noted that some of this difference is due to New Zealand's unique biology and climate.

Stakeholders had diverse views on environmental risk

Environmental stakeholders discussed the environmental risks of products, both with regards to desiring the regime to be strengthened to ensure management of adverse effects (including better monitoring/recordkeeping) and noting that some of these environmental risks do not appear to be managed equally or consistently. R&D stakeholders expressed the view that the environmental risks were managed robustly by the current process, but that biologicals in particular presented challenges to the system because of their persistence and whether they naturally occur in the environment.

Not all stakeholders are aware of potential downstream effects

Environmental stakeholders highlighted that risks are not solely about the point-of-use and expressed concern about downstream effects that products could have on the environment. This contrasted with the concerns raised by horticulture stakeholders who said regulatory assessments sometimes consider species that do not exist in an area.

Environmental stakeholders noted the downstream effects of chemicals introduced into the environment and noted the effects can be cumulative over time and are not always bound to discrete geographical areas.

The regulator should consider benefits as well as risks

R&D stakeholders were interested in the regulator considering the benefits when accessing certain products, not just the risks they pose.

Environmental stakeholders asserted that cost-benefit analyses in general tended to understate the environmental risks and overstate potential benefits. They cautioned consideration of benefits in approvals as they often come with little evidence. Public health stakeholders noted that economic costs should include the impact to human health.

A cohesive framework to understand and prioritise chemicals' risk is lacking

A few environmental stakeholders and agriculture and horticulture associations discussed different ways a risk framework might be applied by the regulators. Some stakeholders, including manufacturers, suggested a common risk framework between both regulators was missing, resulting in inconsistent decisions. One environmental stakeholder considered the intersection of three factors to be critical: scale on which the chemical is being used, potential environmental harm it could

cause, and the extent to which the contaminant's presence is being detected in the environment.

Risk assessment is disproportionate due to lack of understanding

One horticultural association suggested that the regulator does not understand new products, which may be used differently from more traditional ones. They noted the regulator is being overly conservative due to this lack of understanding.

Food quality and reputational risks should be added to assessments

An agricultural association noted that reputational and food quality risks should be considered as part of the regulatory risk assessments, however one stakeholder noted that the regulatory focus should be on actual risks and not perceived risks.

The approval process takes too long

Approvals and reassessments of products are slow and not streamlined

Most stakeholders discussed the speed at which approvals and reassessments were undertaken and the effect it has on their business or the broader landscape. Some stakeholders noted their concern that some companies are not bringing products to New Zealand due to the time that it takes for products to be approved.

They noted that New Zealand's market is not large enough to justify the expense or time involved to seek approval, and so some manufacturers do not apply. This means that products available to overseas competitors are not available to New Zealand's growers and producers.

Some agricultural associations and veterinary organisations were concerned that they do not have access to medicines available overseas and sometimes this leaves veterinarians with no treatment for certain diseases.

Stakeholders discussed their experience with the approvals process and ways they viewed the process to be complex, costly, or slow. Manufacturers and horticultural associations discussed the backlog of applications at the EPA, their view that it was increasing, and the impact of long approval times. Stakeholders considered contributing factors, including (but not limited to) staff shortages, lack of expert capability, inappropriate risk appraisal, staff turnover, and insufficient cost recovery. Manufacturers and agricultural and horticultural associations also reflected these ideas.

Environmental stakeholders contrasted this, noting that the industry sometimes has unrealistic expectations. Agricultural associations suggested that the regulators should be held to the timelines written into statute/regulations as they were in the past.

The system lacks a unified strategic outlook

Industry struggles to develop and access new products

Manufacturers mentioned the challenge of bringing new products to New Zealand due to the regulatory settings. They identified speed of approvals and barriers to trial work as the key challenges. These are further discussed in other sections.

No pathway to test and register products that facilitate biosecurity preparedness

Horticultural producers were concerned that there is no fast pathway to test and register products that support biosecurity preparedness. One manufacturer discussed the merits of a rapid approval pathway for biosecurity purposes.

Reassessments are removing tools faster than they are replaced through new approvals

Agricultural and horticultural associations, exporters, and manufacturers mentioned that there is increasing pressure when products are banned but go unreplaced by newer ones due to the slow approvals process. Some stakeholders speculated that the lengthy reassessment process was exacerbating this issue.

Regulators need to do horizon scanning (foresight of overseas products expected to, or needing to, come to New Zealand)

Many horticultural associations said that it was important to them to access new products, such as biologicals, that support their Integrated Pest Management Systems. Agricultural producers also expressed interest in having access to emerging technologies. Both would like to have pathways to approve these products in place before they are needed. This is important to producers who wish to use newer and often softer chemistry which is less harmful to the environment. A few stakeholders expressed interest in New Zealand being the first place where products are trialled, tested, or used, while noting this is not currently so but some years ago New Zealand was a country of choice for such trials.

Manufacturers and exporters highlighted that an onerous approval process can have a negative impact on investment decisions to bring products to New Zealand at all.

There should be strategic prioritisation of new applications

Horticultural and agricultural associations want the regulator to ensure they do not remove all the tools available to manage a given issue before they are replaced with new ones, and feel it is important that the regulators find a way

to prioritise approvals where there are other tools being phased out.

Regulators should learn from and aligning with international regulators and their regulatory systems

Many industry stakeholders said that the regulators should give more attention to adopting trends or harmonising with international regulators. A few stakeholders mentioned specifically aligning with the CODEX model. Stakeholders wish to avoid unique regulatory requirements or duplication of effort. Horticulture associations called attention to the minimum standard for scientific evaluation and the increasing body of scientific information as drivers towards pooling resources with international experts.

Agricultural associations raised the challenges of a small market and how we might best leverage developments in other countries and jurisdictions. R&D stakeholders indicated that the domestic process was discouraging producers from coming here. Environmental stakeholders highlighted the need for regulation that supports both national and international environment obligations, such as climate goals. This sentiment was mirrored by several stakeholders who spoke of the influence these obligations have on their businesses.

A few R&D stakeholders suggested there are lessons to be learned from overseas regulators who they perceive to have clearer, faster regulatory frameworks. They identified Australia and Brazil as examples. One stakeholder discussed a specific example where they believe the APVMA (Australian regulator) process added value to the approval process.

The regulatory framework fails to address some products

A few stakeholders among agricultural, manufacturing, and veterinary stakeholders mentioned there was a lack of regulatory framework for certain products which affected how well the regulatory system worked; specific examples included treated seeds and pet foods with functional claims.

The system needs to be updated and future proofed

Harmful legacy chemicals that predate the current regulatory system are still in use

Both environmental groups and horticultural producers raised that the current regulatory setup means that older, more environmentally harmful chemicals, are still in use. Many of these chemicals were transferred automatically from the previous regulatory system to the system created by the HSNO Act. Other chemicals are managed under group standards. Some of these legacy chemicals have never been assessed, and only specifically targeted products are individually reassessed. Newer, softer chemicals which may have fewer environmental impact must go through the lengthy approval pathway – which

means in the interim these older, but approved, chemicals are still used.

Public health stakeholders said that the process to get something that is identified as harmful assessed (or reassessed) is too long, and it affects how long it takes to put interventions in place.

The legislation is interpreted narrowly or incorrectly

Agricultural and horticultural associations, manufacturers, veterinary organisations, and environmental stakeholders had different views on the way the regulators interpret current legislation when making their decisions.

For example, some stakeholders believe that the definition of "environment" should also include the communities that would be affected if the nearby horticulture businesses are no longer viable. Largely, those stakeholders who viewed the legislation as inappropriately applied focused on how the regulatory framework considers risk. Other examples raised were exemptions under ACVM and the EPA's interpretation of "significant new information," which is used to trigger a reassessment. One manufacturer claimed it is unclear on the legislative basis the EPA uses to carry out HSNO reassessments.

The system lacks adaptability to change

The regulatory system is outdated and does not easily allow for modernisation

Some stakeholders expressed a view that the current system is outdated and cannot keep up with the speed needed to reassess controls or conditions of older approvals, and some controls are outdated. One example of an outdated approach a stakeholder mentioned was the requirement to publicly notify certain aerial operations in a local newspaper.

Some exporters expressed the view that our regulatory systems were falling behind other countries/competitors and that this ground was going to be difficult to make up.

Producers lack access to innovative tools

Many stakeholders commented on specific tools they have difficulty accessing through the current regulatory framework.

- **Inhibitors:** Most stakeholders discussed inhibitors, which reduce methane and nitrous emissions from stock, and how they fit in the regulatory framework. Stakeholders noted they are important to helping industry meet climate-related goals and commitments and to respond to pressures applied by their supply chains.

  Some suggested it may be important to create a separate path for approval as the efficacy of these products is more difficult to quantify. Some

viewed inhibitors as different from other categories of products in the approval framework, with one stakeholder suggesting efficacy should not be considered. One R&D stakeholder noted that it is challenging to develop emissions-reducing tools for pasture-based farming systems, and that New Zealand farmers are at risk of falling behind other countries who can use other methods to reduce emissions.

- **Biologicals:** Several manufacturers, agricultural associations, and R&D bodies addressed access to biologicals. They noted there is a lack of clear guidance and no appropriate pathways (the "new organism" pathway that currently exists is too difficult) for these products to be approved and assert that any pathway needs to be clear and aligned with international practice. They are eager to use this new technology in concert with other solutions within their crop protection programmes.
- **New Organisms:** Agricultural and horticultural associations discussed challenges bringing whole new organisms, like beneficial insects, into New Zealand under the current regulatory regime. They discussed ways they found the process difficult and time-consuming and how it affects producers' ability to access improved products and technologies.
- **Drones and technology:** Manufacturers and horticultural producers expressed interested in new technologies, like using drones to spray chemicals, and want more guidance from the regulator on how best to employ them.
- **Autologous vaccines:** One stakeholder discussed autologous vaccines, where tumour matter from an individual animal is incorporated into a vaccine and dosed back into the same animal. Because there is no single formulation for these types of vaccines, there is currently no way to progress them through the approval pathway.

There are barriers to trial work and research

Manufacturers and agricultural and horticultural associations discussed their difficulties undergoing trial work, citing issues such as limited approval periods for research, environmental conditions and animal behaviour, the number and role of agencies involved in the approvals, the length of time trials take, and the difficulty of maintaining records in partnership with farmers.

A few stakeholders among horticultural associations and other groups mentioned ways the current EPA processes introduce difficulties to doing the research required to satisfy the regulators – the length of time it takes to gain approval to trial new substances being a key pain point. They mentioned this was exacerbated by New Zealand's small market size.

Product use can affect market access

Several horticultural associations discussed how Maximum Residue Limits

(MRLs) restrictions and public perception can limit the markets they can access. Increased public access to product testing and publication of their findings means companies must react quickly to public perception issues. As an example, stakeholders specifically mentioned glyphosate and its hazard classification, which is different to that in Australia, to illustrate the importance of having internationally accepted standards.

The system appears fragmented and poorly coordinated

The regulatory system appears to overlap

A few stakeholders, including agricultural and horticultural associations, other stakeholders, and manufacturers perceive overlap between the ACVM and HSNO regulatory systems, and as a result it makes the system more complex and difficult for the end-user to follow. Some examples included applicants needing to provide similar information to both regulators, the same information being assessed in different ways, and the EPA asking questions about efficacy when the applicant believed responsibility for this lies solely with NZFS.

Agricultural and horticultural associations, manufacturers and environmental stakeholders referenced other legislation they must comply with when using certain products, and the challenges associated with that compliance. They also noted there are broader systems at play, including industry initiatives and international regulatory mechanisms such as Codex.

The regulators appear to be duplicating the work of international regulators or not using their expertise

Many agricultural and horticultural groups, R&D bodies, and manufacturers discussed ways they thought the regulators were duplicating work that had already been done overseas. They asserted that some trial work/research is unnecessarily duplicated, or that the regulators should be adopting decisions made by trusted international regulators to avoid this duplication, with some considering this approach could be combined with having the regulators focus only on risks specific to New Zealand. One stakeholder mentioned that the European Union is working towards restricting import of produce treated with products no longer registered in their market, highlighting the importance of being internationally connected.

Requirements can be complex and unclear

Many agricultural producers and some manufacturers expressed the view that the approval path was unclear and complex. Stakeholders specifically mentioned timeframes, testing criteria,

overall cost, and lack of guidance as contributing factors. One stakeholder said that in addition to the complexity of the requirements themselves, there was inefficient use of limited resources and distrust of the end-users of the products. One stakeholder noted that the toxicology requirements were unclear.

Uncertainty and lack of visibility of approval process

Stakeholders expressed frustration about the lack of visibility of where their products were in the approval process. One agricultural association noted that the design of the engagement process forced them to lobby for support.

Stakeholders, including horticultural associations and others, mentioned uncertainty around the approval process regarding timeframes and whether the information submitted in their application is sufficient to gain approval. One noted they do not always know when more information is required until many months after submitting the application, which is time they could have spent gathering that data.

R&D bodies and other stakeholders noted that the regulator was not providing the appropriate level of help to navigate the process. They mentioned complexity and delays. One manufacturer noted that not knowing what pathway their product will gain approval under makes it difficult to estimate costs.

Agricultural associations said they want a more streamlined application process and supported more timeline transparency. This is important to their own processes and resourcing for business planning purposes.

Inconsistent advice/ interpretation of legislation

Manufacturers and agricultural producers commented that they have received conflicting advice from regulators regarding the legislative requirements. Some stakeholders stated they feel the discretion the regulators are allowed in interpreting legislation/guidance leads to subjective inconsistencies, with one stakeholder noting instances where some products assessed as exempt from a class by NZFS were later assessed as non-exempt. Other stakeholders, including from veterinary organisations and manufacturers, suggested the legislation is too prescriptive and there is not enough flexibility.

Environmental stakeholders highlighted gaps and lack of information sharing by EPA and other regulators and industry which could contribute to applicants' perception that the regulators are inconsistent.

Regulations can overlap with industry programmes

Stakeholders expressed conflicting views on the value of industry-led programmes such as Good Agricultural Practice (GAP) schemes and other guidance. Horticultural producers submitted that, in some cases, they go further than regulatory systems and are rigorously audited. Environmental groups assert that the incentives for industry players to do what they say they will do is not in

place, and that often industry-led programmes are not as robust as stated.

Better engagement communication and guidance are needed

Stakeholders want more and better engagement

Some agricultural stakeholders highlighted NZFS and the EPA's willingness to engage and assist applicants through their respective processes with forums, guidance, diagrams, and templates.

Many stakeholders, including horticultural associations/exporters, suggested that the EPA did not communicate well or listen to their feedback. They discussed instances where they provided the EPA with information but received limited feedback on whether it was what they needed. Stakeholders indicated that having better direct engagement with the regulator would improve outcomes. One stakeholder claimed that some manufacturers and importers are completely unaware of their obligations under HSNO.

Horticultural associations and manufacturers also indicated a lack of communication around timelines and process clarity. A few stakeholders, including veterinary organisations, had similar comments regarding ACVM. They noted a lack of transparency and communication, or that they were not signalling their requirements appropriately.

One stakeholder recommended that the regulatory system needs to better support the identification of risks to Māori cultural values. They suggested more pre-engagement with relevant parties to assess the impacts of products on Māori values and interests.

The regulator does not understand the industry sufficiently

A few agricultural and horticultural associations suggested that the EPA does not have a good understanding of their industry and does not acknowledge industry-led risk management. Horticultural producers suggested that the regulators had limited understanding about how fruit and vegetables are grown and the daily challenges they manage.

The regulators should collaborate more closely with industry

Some agricultural and horticultural associations asserted a need for the regulator to collaborate with industry to help them address their issues that are unique to New Zealand's farming systems. One manufacturer suggested the regulatory system align with industry initiatives, such as Growsafe, a certification scheme for those who use agrichemicals. Horticultural associations also reinforced the idea that the regulator

and industry should work closely together.

Some guidance the regulator could provide is missing or difficult to obtain

Manufacturers, R&D groups, horticultural associations and others submitted on written guidelines they feel are missing, such as process flow charts, guidance on registering biologicals, toxicology and efficacy requirements; a few stakeholders mentioned wanting more direct support during the application process, with one suggesting a dedicated pre-application team.

Some stakeholders appreciated the existing ability of NZFS to consult directly with applicants and found their advice invaluable, others wanted this extended into a new service, and some suggested that they did not work with them as collaboratively as they worked with other parties. One stakeholder said that it would be helpful if NZFS published a list of other regulators' guidelines they might use when making assessments. Some stakeholders acknowledged that much of this support requires the regulators to have adequate resourcing (including funding and expertise).

Horticultural associations also noted that the EPA's process was unclear and lacks transparency, which could be addressed using guidance.

Some guidance the regulators provide is out-of-date

Stakeholders discussed regulator guidance and their view that it is out of date. Veterinary organisations, horticultural associations, and other stakeholders spoke of contradictions, unexpected references to overseas guidance where local guidance was not available, unclear data requirements, and guidance not accommodating new product types, such as inhibitors.

Parts of the system are not fit for purpose

ACVM data assessment is not working as intended

Veterinary associations, R&D bodies, manufacturers and some assessors, themselves, discussed many aspects of using external data assessors as a component of the regulatory system. This included appropriate training and accreditation, the quality/consistency of their work, whether their work was being duplicated by the regulators, and the global shortage of assessors. Most stakeholders said the function was critical and, generally, that there should be more rigour around them. Stakeholders also considered whether the function should sit in-house with NZFS and whether a conflict of interest exists when data assessors are paid by the chemical manufacturers.

Stakeholders also raised the independence of data assessors and how conflicts of interest should be managed. Public health stakeholders noted that training and accreditation is important and that the age-profile of existing assessors could result in a sudden capability shortfall upon their retirement.

The EPA uses outdated models to undertake risk assessments

Agricultural and horticultural associations, exporters, and environmental stakeholders were among those concerned about the outdated nature of the toxicity and ecotoxicity models used by the EPA, asserting that it was forcing the EPA to put greater controls on products to manage the risks they could not accurately model. Most stakeholders said that for them this meant they either could not access products, or the EPA's assessments were out of step with comparable regulators overseas. One environmental stakeholder called attention to the lack of New Zealand-specific inputs to EPA models.

Lack of or limited data protection for applicants

The lack of data protection under HSNO was highlighted by many stakeholders, some of which also claimed this was a major concern and source of process inefficiency, as they must register first with ACVM to get data protection. This means submitting an incomplete application and leaving it sitting with NZFS in their queue while they submit their application under HSNO.

Some manufacturers and agricultural associations believed existing data protection through ACVM does not last long enough and should be extended, especially since the approval timings have increased. They suggested this would help them recover R&D costs for new products. One manufacturer mentioned that, while reassessments were financially burdensome, they were made more so by the lack of data protection during that process.

Data freeriders

Some stakeholders raised the issue of so-called "freeriders" where similar chemistries to existing products can gain approval by using the data about those existing products. Because the costs of generating data are borne by the applicant, many industry stakeholders expressed their need to protect the data to recover their costs. However, some stakeholders were conflicted about placing preference on confidentiality because if the system allowed use of this data for later applicants, it is likely to speed up the approvals process.

Treatment of commercially sensitive information

A few stakeholders discussed the importance of protecting commercially sensitive information, with one stakeholder citing an instance where the regulator released information that they had requested be kept private.

Product labelling requirements

Harmonising labels between NZ and AU markets

Manufacturers were interested in ensuring labelling is harmonised with Australia so that New Zealand quantities could be included in Australian manufacturing orders, which would reduce their costs. Stakeholders asserted the current difficulty of this process puts New Zealand at risk of losing access to critically important veterinary medicines.

Increasingly restrictive controls threaten growers' ability to use products off-label

Several manufacturers and horticultural associations discussed using products in ways that are not specified on the label. Stakeholders asserted that some label controls limit the options for products they can use, especially for smaller crops, and that often the cost to expand the label to include new uses exceeds their returns. One said a consequence is that industry continues to use older and often more toxic chemistry as it has less stringent controls.

Stakeholders also raised how industry manages off-label risk through use of the Good Agricultural Practice (GAP) schemes. Horticulture producers indicate that the schemes provide guidelines for growers to use products without exceeding MRL and thus the industry self-limits the risk from this type of use. One stakeholder mentioned that while they were allowed this type of use under ACVM, since the EPA has started putting crop-based controls on products, this is no longer possible.

Verifying label claims adds time and cost

Manufacturers and horticulture associations spoke about how difficult it is to assess product efficacy within New Zealand. They believe that if a product is ineffective, growers will not purchase the product, and it will eventually exit the market. They also pointed out that ACVM does not reassess a previously registered product if something more effective enters the market, or if resistance develops to a product. For these reasons, they believe efficacy assessments should not be part of ACVM registration.

Label requirements onerous/not coordinated between regulators

Many manufacturers and some horticultural associations discussed the ways in which they view the process around labelling to be difficult or not coordinated across both regulators. They also noted that where labels require a change the requirements to do so, for the size of the market, can discourage suppliers from going through the process at all. One mentioned the process for labelling treated seed can contribute to delays or prevent exports entirely.

Stakeholders noted that overlapping roles (between ACVM and HSNO) related to product labelling is confusing and complex and can lead to inaccurate information and incompatible use restrictions. Additionally, one horticultural association noted they have seen labels with incorrect EPA-related information, including HSNO approval codes.

Some regulations are too onerous

The regulatory requirements to gain approval are too onerous

Some manufacturers, agricultural and horticultural associations, and R&D bodies indicated that some regulatory requirements are too onerous. Stakeholders highlighted what they saw as excessive data requirements and the costs of generating that additional data eroding sustainable profit margins. Other stakeholders indicated the regulator does not ask for enough information to understand real-world impacts, and that

there are risks of applicants cherry-picking data.

Several stakeholders discussed how the requirements are applied to veterinary pharmaceuticals. One said that, in broad terms, the focus on quality assurance of veterinary pharmaceutical chemicals was excessive when applied to managing risks of animal feed. One manufacturer noted that for some externally used products, or products designed for companion animals, there is no trade risk present. Some stakeholders discussed the way veterinary medicines are treated in the current regulatory system. For example, a stakeholder said they should be excluded from HSNO but if regulations did not change, it was important for NZFS to retain key experienced staff so they can continue to take a pragmatic approach to these products.

One horticultural association said that the current regulatory system does not support the government's stated goal of doubling exports.

Permitted uses are too restrictive

One horticultural association said that the approvals system was too restrictive, and wanted the ability to obtain something akin to minor use permits available in other jurisdictions, so they could use a larger number of products off-label, especially on smaller crops where obtaining specific approval is too costly. They said that the industry advice and controls in place would help to self-regulate this type of use. One stakeholder made a similar point regarding the exemption and class determination systems, stating they were "overly restrictive" and could take a different approach with lower risk products. Stakeholders' views on a different framework for lower risk products is discussed further in the section on risk.

The regulators lack enough trained staff

A few stakeholders commented on the regulators' staffing levels. They noted that insufficient staffing levels are affecting the speed of assessment and reassessment processes. Manufacturers and environmental and public health stakeholders noted that getting the expertise and skills required to evaluate products is difficult – and worse again because we require expertise specific to New Zealand's unique challenges. They advocated for attracting the appropriate assessment and toxicology talent and commented on the constrained availability of capability in this field worldwide.

Agricultural associations and environmental stakeholders raised under-resourcing issues with both regulators, and agricultural associations discussed the balance of resourcing directed towards assessments versus reassessments. Public health stakeholders highlighted the need for up-to-date models, and the lack of toxicologists and independent analysists. Manufacturers discussed general capability and staff turnover.

Manufacturers also noted they are unsure about the staff composition and expertise on governance boards at the regulators and wondered if they have people with commercial experience.

3. Specific issues raised

Hemp

Many stakeholders discussed the barriers the regulatory systems pose to the hemp and hemp byproduct industries. Stakeholders included manufacturers and growers, public health and environmental groups, and others. Among those others were individual industry supporters, academics, journalists, and consumers. Stakeholders expressed similar views on expanding the industrial hemp industry and the benefits of doing so, including growing local opportunities and new revenue streams, supporting sustainable agricultural practices, and carbon sequestration.

Stakeholder comments on residue levels in animal products where hemp products are used in feed and the potential trade/market implications of those residues were relevant to the Review.

Apiculture

Apicultural stakeholders expressed views similar to other agriculture and horticulture stakeholders with respect to the need to reduce approval times for new products and to streamline and reduce system overlaps. However, they also noted the need to facilitate access to improved products for growers and appropriately managing those risks. They focused on their regular need for new miticides to control varroa mites, which continually develop resistance. Delaying access to treatments has implications for bee health and production. Residues of glyphosate in honey have also presented trade risks in the past, and the apiculture stakeholders stressed the importance of good exporting standards, continued management of New Zealand's reputation for safe food and a greater understanding of how residues are found in honey.

Pest control

Several stakeholders in the pest control industry, including stakeholders who focus on aquatic, horticultural, or environmental pests, commented on their need to have multiple products available, particularly to deal with New Zealand-specific pests, and the speed of approvals.

Some detailed the challenges they encountered with the approval process and the need to obtain three or four approvals (if on Department of Conservation land) to conduct field research. Because the approvals are time limited, if their approval period lapses due to delays or other factors, they must start again.

One stakeholder noted that only two vertebrate toxic agents (VTAs) have been approved in 13 years. This stakeholder suggested New Zealand is in a biodiversity crisis and has problems that are different from those the products were developed to address. For that reason, there is a need for New Zealand to develop more bespoke solutions.

Product resistance

Many horticultural associations discussed how their industry is impacted by product resistance. They noted that it drives a need for constantly evolving products and technology. This flows into their discussions on the speed of approvals, the need for specific expertise from the regulators, and their ability to compete in international markets. A few stakeholders mentioned the regulatory system influencing whether they develop products locally.

Hi-Cane

Some stakeholders mentioned Hydrogen cyanamide (Hi-Cane), a plant growth regulator widely used in New Zealand. Because it was the subject of a public consultation process, with those submissions publicly available[4], we have not sought to reflect all of those views in this report.

Regulator cost recovery

Manufacturers and environmental stakeholders expressed views on the funding levels for both regulators, the allocation of that funding, and their view that the EPA's functions are under-recovered. Some expressed the view that EPA could be more efficient with the resourcing they have. Environmental stakeholders generally agreed that the EPA's cost recovery should be increased.

Exporters and agricultural and horticultural associations expressed a desire for more transparency of the use of cost-recovered funds and the impact of those funds on the regulator's services to industry, who pay those costs.

[4] https://www.epa.govt.nz/public-consultations/decided/hydrogen-cyanamide-reassessment/

4. Out of scope issues

The Review's TOR identified some matters that were out of scope of the Review. Some stakeholders commented on those matters. For completeness, we have included their comments in this report, and they may be considered for future work on these regulatory systems.

Regulation not directly covered by the ACVM and HSNO regulatory systems

Some stakeholders commented on regulatory systems that intersect with ACVM and HSNO. They included:

- Health and Safety at Work (Hazardous Substances) Regulations 2017
- Animal Products Act 1999
- Biosecurity Act 1993
- Regional / District Council Plans (Land, Air, Water) or Conservation Management Plans/Strategies and National Park Management Plans
- Resource Management Act (Exemption) Regulations 2017
- Department of Conservation Permissions
- Medical Officer of Health Permissions
- Misuse of Drugs Act 1975

They noted that these intersecting systems impact their use or trialling of agricultural and horticultural products. They indicated that in some cases, legislation and linkages between the different pieces of regulation were not sufficiently robust.

One stakeholder highlighted that these intersecting systems (including Animal Ethics and the Department of Conservation), combined with animal behaviour and environmental conditions, makes R&D trials resource intensive and lengthy. Further, because containment and research approvals are time-limited, if these factors cause delays beyond the approved time, researchers must seek new approvals which has cost implications for their business.

Other functions of the regulatory system (monitoring and compliance)

Many stakeholders from R&D bodes, public health, environmental, and veterinary groups and manufacturers expressed the view that there is insufficient monitoring and enforcement activity for agricultural and horticultural products. Some stakeholders highlighted that no data is collected on product sales and use, resulting in poor auditing.

Environmental stakeholders expressed the view that New Zealand lacks the information needed to appropriately manage the risks of chemicals in the environment. They noted that without

monitoring, harm continues without detection. One stakeholder mentioned some products with non-exempt claims being on the market for some time before enforcement action was taken.

Several stakeholders mentioned areas where New Zealand could learn from international practice and provided examples such as a Pollution Release and Transfer Register, a national data collection platform which joins dots between permitted discharges and monitoring and traces of contaminants. One environmental stakeholder noted that the environmental fate of some contaminants is poorly captured or missed. They said this is due in part because the regulators have not been given the power to collect sales information.

Appendix 1: Organisations that made submissions

Agrizero

AgResearch

Animal and Plant Health New Zealand (APHNZ)

Animal Medicines Australia

Apiculture NZ

Apple and Pear Board

Balance

Bayer New Zealand

Beef & Lamb NZ

The Brothers Green

Buzz Club Otaki

CH4 Global

Dairy Companies Association of New Zealand (DCANZ)

DairyNZ

dsm-firmenich

Environmental Defence Society

Environmental Law Commission

EpiVets

Farmers Fruits

Federated Farmers

Feed Ingredient and Additives Association of Australia (FIAAA)

Fertiliser Association of New Zealand (FANZ)

FMC New Zealand

Fonterra Co-operative Group Limited

GLA Pharma Ltd

Hale Animal Health

HortNZ

International Accreditation New Zealand (IANZ)

Jaychem

Mars NZ and Royal Canin

Midlands Seed Ltd

Ngai Tahu HSNO Komiti

New Zealand Grain and Seed Association (NZGSTA)

New Zealand Medicinal Cannabis Council

New Zealand Kiwifruit Growers (NZKGI)

NZ Hemp

NZ Pork

NZ Veterinary Association

NZ Wine

Orillon

Parklink

Parliamentary Commissioner for the Environment

Petfood NZ

Ruminant BioTech

Syngenta

Tasmanian Hemp Association

UPL New Zealand

Venture Taranaki

Waikato District Council

Waikato Regional Council

Zero Invasive Species

Zespri