Minister for Regulation

Information Release

Terms of reference for the approval path for agricultural and horticultural products regulatory review

September 2024

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1	2024-034 (Excerpts only)	Briefing excerpt	Advice on next sector reviews	31 May 2024
2	2024-049	Note	Talking points on potential sector review into agricultural products	7 June 2024
3	2024-053	Note	Next steps for the agricultural products regulatory review	14 June 2024
4	2024-059	Briefing	Draft terms of reference and Cabinet paper for the Agricultural Products Regulatory Review	24 June 2024
5	2024-070	Note	Summary of consultation feedback on the terms of reference and Cabinet paper for the Agricultural Products Regulatory Review	9 July 2024
6	2024-076	Note	Talking points on Agricultural and Horticultural Products Regulatory Review for EXP	18 July 2024
7	EXP-24-SUB-0033	Cabinet paper	Terms of reference for the approval path for agricultural and horticultural products regulatory review	23 July 2024
8	EXP-24-SUB-0033-A	Cabinet paper attachment	Terms of Reference for the agricultural and horticultural products regulatory review	23 July 2024

#	Reference	Type	Title	Date
9	EXP-24-MIN-0033	Cabinet Committee Minute	Cabinet Expenditure and Regulatory Review Committee Minute of Decision	23 July 2024

Information withheld

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Executive Summary

We have explored several potential areas that could be the subject of the next sector review. We have identified two lead sectors – agricultural compounds [*redacted s 9(2)(f)(iv)*] – that we think could be suitable for the next sector review. There are several options for the scope of these reviews.

Recommended Action

On Agricultural Products we recommend that you:

Note that there are already several processes reviewing parts of the path to market for agricultural products, and that the Agricultural Compounds and Veterinary Medicines regime was reviewed in 2021-22 by the Ministry for Primary Industries' Inspector General for Regulatory Systems;	*Note*
Note that there is merit in a review that considers the system as a whole for approving products for use in agriculture, including the approval pathway across different regulatory systems and taken from the perspective of regulated parties;	*Note*
Agree to meet with Ministers Hoggard and Simmonds to discuss i. The need for considering the approval pathway for products across these regulatory systems, and the perspective of regulated parties throughout that process; ii. The potential for a sector review as outlined in paragraph; iii. Alternatively, what changes could be made to existing or planned reviews that would address the concerns raised; iv. Whether they would be willing to issue a direction to their agencies to work with the MfR on this work, given the other priorities for their agencies.	*Agree / Disagree*
Note that we think there will be some merit in reviewing issues that cut across multiple sectors, such as occupational licensing and cost recovery policies.	*Note*

Products for use in agriculture

Following your direction we have carried out initial scoping work on the path to market for agricultural products, with a particular focus on the Agricultural Compounds and Veterinary Medicines (ACVM) and Hazardous Substances and New Organisms (HSNO) regulatory regimes.

We have confirmed that the path to approval for agricultural compounds is complex, spanning several regulatory systems and regulators, and takes considerable time. Issues we have heard from sector include:

a. Considerable time required to secure approvals;

b. Significant evidence requirements;

c. Apparent under-utilisation of approvals by international regulators;

d. Complexity in navigating the different regulatory systems;

e. Perceived risk culture of regulators;

f. Costs to the sector, both in data collection and resourcing through the application process, and also in the opportunity cost due to delayed access to the products.

There are already several review processes underway across parts of the systems, including:

a. Comprehensive reform of gene technology regulations and creating a new biotechnology regulator (led by Minister Collins). We understand initial policy decisions are to be considered by Cabinet in August to begin drafting the legislation.

b. An independent review into the ACVM regulatory regime focussed on streamlining and efficiency (led by Minister Hoggard). The review is intended to be completed by the end of 2024.[1]

c. An intended review to streamline approvals of hazardous substances, and subsequent changes to the HSNO regime following removal of the gene technology regulation (led by Minister Simmonds). Initial advice on these topics is still being developed.

d. An existing operational forum of government officials (Ministry for the Environment, Ministry for Primary Industries, Environmental Protection Authority), representative bodies and inhibitor companies to understand regulatory pathways for greenhouse gas inhibitors.

[1] This review is on hold while the Ministry for Regulation undertakes its current review

A Regulatory System Review into ACVM was undertaken between June 2020 and June 2021 by the Ministry for Primary Industries' Inspector General Regulatory Systems.

There are benefits in the reviews of ACVM and HSNO within each system, and also the importance of a comprehensive review of gene technology regulation given the time since this was last undertaken.

Despite these initiatives, we think there is merit in a review that considers the system as a whole. This could include considering the product approval pathway *across* these systems from the perspective of regulated parties. Given the number of existing systems and moving pieces, there may also be benefit in a single piece of work that sits across all of these and that provides an independent perspective.

A potential sector review could have the following parameters:

a. *Scope*: Review the path to market for products for use in agriculture (including fertilisers, feeds, inhibitors, veterinary medicines, and new organisms).

b. *Approach*: The review could be guided by:

    i. The approval pathways for an indicative set of products, and assessing the issues and barriers encountered for each of those. This could include considering specific products that are not yet available in New Zealand, products that had a particularly difficult or complex process to gain approval, and other products that might test the limits of the process.

    ii. The perspective of regulated parties navigating these systems, and the issues they have encountered and observed. Issues experienced by regulators would also be considered as part of this.

c. *Relationship to existing processes*: This would be expected to sit across and inform the relevant reviews and any subsequent changes to ACVM and HSNO. There may need to be some limited connections to the reform program for gene technology, but this would largely sit alongside that process.

d. *Timeline*: Provided appropriate approvals could be received, a review could be announced in June to start in August (allowing time for scoping and commissioning).

An alternative to a sector review would be for the existing and planned initiatives (paragraph 9) to be amended to emphasise the product approval pathway

through the multiple regulatory systems and the perspective of regulated parties. Given the cross-portfolio nature of the multiple regulatory systems, achieving a cohesive approach independent of a sector review may be difficult.

We expect the proposed sector review could be approved by the relevant portfolio Ministers (Hon Andrew Hoggard for Biosecurity and Food Safety; Hon Penny Simmonds for Environment) and yourself, rather than needing approval by Cabinet. Your office may wish to confirm this understanding with the Prime Minister's Office. You may also wish to discuss this with other ministers with an interest, including Hon Judith Collins KC (Science, Innovation and Technology) and Hon Todd McClay (Agriculture).

We recommend you meet with Ministers Hoggard and Simmonds to discuss:

a. The need for considering the approval pathway for products across these regulatory systems, and the perspective of regulated parties throughout that process;

b. The potential for a sector review as outlined in paragraph 13;

c. Alternatively, what changes could be made to existing or planned reviews that would address the concerns raised in paragraph 14;

d. Whether they would be willing to issue a direction to their agencies to work with the MfR on this work, given the other priorities for their agencies.

We can provide additional material to support you in these meetings as necessary.

Next Steps

If you agree with recommendations in this paper we will provide you with further briefing materials in advance of any meetings with other Ministers.

NOTE

Ministry for Regulation

Minister and Portfolio:	**Hon David Seymour, Minister for Regulation**		
Title:	**Talking points on potential sector review into agricultural products**	**Number**	**2024-049**
Date:	**7 June 2024**	**Security Level:**	**IN CONFIDENCE**

Purpose

Provide you with talking points and background information on a potential sector review into agricultural products to support your discussions with Ministers Hoggard, Simmonds and Collins in the week of 10 June. This also sets out next steps if a review is agreed by Ministers.

Background

Regulatory systems

The approval path for agricultural products is currently being investigated as an area for the next sector review. The relevant regulatory systems are:

- Agricultural Compounds and Veterinary Medicines (ACVM), run by the Ministry for Primary Industries (MPI), requires anything that is to be used for or on plants or animals to be regulated. This includes feed, fertiliser, veterinary medicines, herbicides, greenhouse gas inhibitors and rodent poisons.
- If the product also meets the threshold of being a hazardous substance or a new organism, then it will also need approval under Hazardous Substances and New Organisms (HSNO), run by the Environmental Protection Authority (EPA). This includes any products that are corrosive, flammable or toxic, that are new to the country, or have involved genetic modification.
- With the Gene Technology reform program, it is expected that any products, including **some agricultural products**, involving genetic modification would be regulated under the proposed Gene Technology Bill and a new regulator, instead of HSNO/the EPA as is current. This could include some animal vaccines, which would need regulation under both ACVM and Gene Technology.

Collectively, these regulatory systems seek to manage risks to: public health, through the safety and suitability of food; trade, including through ensuring confidence in NZ's food safety regime; agricultural security; animal welfare; and the environment.

The path to approval is inherently complex because of the several regulatory systems, with the properties of a specific product influencing which regimes are relevant. In practice, an application under ACVM is paused at a certain step until the EPA has completed their assessment under HSNO, before being resumed under ACVM. How the Gene Technology regime will interact with the other systems is still to be defined.

More detail on these regulatory systems has been provided for your reference (**Appendix A**).

Problems identified

Agriculture sector representatives have raised several problems with how the current approval path is operating, including:

- The estimated 5-9 years it takes to get approved (which includes data collection);
- That we aren't leveraging approvals by equivalent regulators better;
- The risk culture of the regulators; and

- The complexity in navigating the different regulatory systems.

They have noted s 9(2)(b)(ii) and newer cyanamides (plant growth regulators that supports budding of plants in horticulture) as specific products that are not currently available in New Zealand.

The sector has identified that timely access to new products is important to the agriculture sector so that it can:

- Maintain productivity and agricultural security – as the efficacy or existing products decreases, or as pests and bugs become resistance to existing chemicals;
- Grow productivity and exports – *could* add additionality through access to newer and more effective products;
- Reduce side-effects of current products – through accessing newer products with improved impact (e.g. on the environment).

A potential review into the approval path for agricultural products

A review could:

- Consider in scope all agricultural products that are currently regulated under ACVM and HSNO, including those that involve genetic modification;
- Review the design and operation of ACVM and HSNO, but not the design (or future operation) of Gene Technology as this is subject to a separate process;
- Consider the interfaces and any overlaps between the three systems;
- Be guided by issues encountered by regulated parties and regulators;
- Sit alongside Gene Technology reform but be connected with and inform the review processes underway or planned for ACVM and HSNO; and
- Be reported to joint Ministers, but be led by the Ministry for Regulation with input from the other agencies.

Given the issues raised by stakeholders to date regarding HSNO and the overlap of the two systems, it is critical that any review has both HSNO and ACVM in scope.

A joint approach would be more impactful

A joint approach will be beneficial to leverage the expertise of other agencies, and would be expected to have mutual benefit for the other portfolios, including:

- **Food Safety**:
  - Improving access to products with reduced risks for food safety;
  - An independent review of ACVM;
  - Chance to streamline approvals across the regulatory systems; and
  - Chance to improve processing times under HSNO, which would improve the timeframe for ACVM approval.
- **Environment**:
  - Improving access to products with reduced impacts on the environment;
  - An independent review of HSNO;
  - Chance to streamline approvals across the regulatory systems; and
  - Supports the action in the *Harnessing Biotech* policy document to '*Streamline approvals for trials and use of non-GE/GM biotech*'.

	• **Science, Innovation and Technology**:
	  ○ While the Gene Technology reform is focused on establishing the new system, a review could complement this by focusing on how that system would fit with ACVM and HSNO;
	  ○ May provide an opportunity to address any changes needed in ACVM or HSNO to support the operation of the new regime;
	  ○ Supports the action in the *Harnessing Biotech* policy document to '*Streamline approvals for trials and use of non-GE/GM biotech'*; and
	  ○ Any lessons learnt from a review of ACVM and HSNO could be fed into the design process for Gene Technology.
	
	We have initial support from MPI and the Ministry for the Environment for a joint approach.

General talking points	• Stakeholders from the agricultural sector have come to me with some compelling problems about how long, difficult and complex it is to get new products approved in New Zealand. • I understand they don't have access to products available in equivalent countries and have fewer products available to support productivity and to counter biosecurity risks. • Approval for agricultural products sits across two, and soon to be three, regulatory systems, with no one agency or Minister able to look across these. • I think there is merit in us undertaking a joint piece of work that looks across these systems, ensuring our regulations are doing what they need to while also unlocking productivity and innovation. • I am mindful that you and your agencies are busy with your other priorities, but I can contribute some capacity from the Ministry for Regulation to lead this joint work. • Are you willing to explore a joint project on approval pathways for agricultural products? • Are you willing to direct your officials to work with the Ministry for Regulation to scope up this joint work?
For meeting with Minister Hoggard	• This is a chance to address issues across both ACVM and HSNO, which no one minister currently has the ability to do. • Chance to provide an independent perspective on how ACVM and HSNO are operating. • This can help streamline the approval path for agricultural products, meaning farmers and growers have access to new products faster. • The review could connect with, and feed into, other reviews and changes you may have planned for ACVM.
For meeting with Minister Collins	• Some agricultural products, for example vaccines, may ultimately need approval as genetic technologies, in addition to approval as a veterinary medicine. • While we would consider the products in scope of a review, **we would treat the Gene Technology regime itself as out of scope** – I have no intention of this review impacting your reform program. • A review could complement the reform program by considering the interface of the three regulatory systems, and any changes in ACVM and HSNO that would support the reform. • This would support the priority of streamlining approvals for trials and use of non-GE/GM biotech, and can connect in with any work underway on this. • Any lessons learnt from a review of ACVM and HSNO could help inform the design process for the Gene Technology regime.

For meeting with Minister Simmonds	• This is a chance to address issues across both ACVM and HSNO, which no one minister currently has the ability to do. • Chance to provide an independent perspective on how ACVM and HSNO are operating. • This would support the priority of streamlining approvals for trials and use of non-GE/GM biotech, and can connect in with any work underway on this. • The review could connect with, and feed into, other reviews and changes you may have planned for HSNO.
Additional talking points	*Sector reviews* • Sector reviews are a new tool to improve the quality of our regulations and free up our productivity and innovation. • They will provide a chance to step back and take a hard look at why and then how we are regulating parts of the economy. • These intend to answer some fundamental questions of regulation, including what the problems and market failures are, what are the costs and benefits, and are they working. *Potential approach for agricultural products review* • There is benefit in a review that considers the system as a whole, and from the perspective of regulated parties who are trying to navigate their way through. • The full range of products farmers and growers want to use on their property could be considered - including feed, fertilisers, veterinary medicines and inhibitors, and those that might need approval as a hazardous substance or gene technology. • Rather than a comprehensive approach, this review could focus in on the issues encountered by regulated parties, and also where regulators know things aren't working. • This review could sit alongside the important and timely reform of gene technology and be connected with and inform the various reviews underway or planned for each system. • The Ministry for Regulation could lead the review, providing an impartial viewpoint throughout, but with close collaboration from your agencies. • Our respective officials should take a bit of time to map the pathways for different products and plan out a review, with relevant ministers then making decisions on it.
Next steps	You may wish to confirm with the Prime Minister's Office that relevant portfolio Ministers can agree to a sector review rather than needing Cabinet approval. If a review is agreed by Ministers: • Your office may also wish to liaise with the Prime Minister's Office about any announcements at Fieldays; • You may wish to inform the Minister of Agriculture prior to any announcements; • We can provide key messages and develop Q&As to support any announcements if requested; and • We will begin work with relevant agencies to develop a scope and terms of reference for the review, for Ministers' consideration.
Author	Peter Clark, Principal Advisor, Sector Reviews
Manager	David Wansbrough, Sector Reviews Lead, Sector Reviews

Factsheet: Regulatory systems relevant to approving products for use in agriculture in New Zealand[1]

Regulatory system[2]	Agricultural Compounds and Veterinary Medicines	Hazardous Substances and New Organisms[3]	Gene Technology[3]
Legislation	Agricultural Compounds and Veterinary Medicines Act 1997	Hazardous Substances and New Organisms Act 1996	*TBC* (Gene Technology Bill)
Regulator	New Zealand Food Safety (Business Unit within Ministry for Primary Industries)	Environmental Protection Authority	*TBC but expect new regulator*
Policy agency	Ministry for Primary Industries	Ministry for the Environment	Ministry of Business, Innovation and Employment
Responsible Minister	Hon Andrew Hoggard	Hon Penny Simmonds	Hon Judith Collins KC
Purpose	Prevent or manage risks associated with the use of agricultural compounds, being— • risks to public health; and • risks to trade in primary produce; and • risks to animal welfare; and • risks to agricultural security. Ensure that the use of agricultural compounds does not result in breaches of domestic food residue standards. Ensure the provision of sufficient consumer information about agricultural compounds.	Protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms[4].	*TBC*
Regulated parties	Anyone seeking to import, manufacture or sell agricultural compounds or veterinary medicines.	Anyone who imports or manufactures a hazardous substance. Anyone who imports, develops, field tests or releases a new organism[4].	*TBC*
Regulated products	Substances used to help manage plants and animals, including: • veterinary medicines (substances used for animals, including companion animals) • agricultural chemicals (substances used for plants, including herbicides, fungicides, insecticides, plant growth regulators, surfactants, and adjuvants) • vertebrate toxic agents (substances that kill or limit the viability of animals, such as possums, rodents, and other unwanted mammals) • fertilisers, plant biostimulants, and soil conditioners • pet food and animal feed (including dietary supplements) • substances used for the purpose of mitigating adverse impacts on the environment or mitigating emissions that contribute to climate change.	Products, chemicals or mixture of chemicals that has one or more of the following properties: • explosive; • flammable; • oxidising; • toxic; • corrosive; • ecotoxic. New organisms, including: • species that were not present in New Zealand before 29 July 1998 • those with containment approval (eg in a zoo or laboratory) • genetically modified organisms[4] • species that have been eradicated from New Zealand.	*TBC* but expected to include: • genetically modified organisms • gene technologies.

[1] Scope is intended to cover the approval to use the products, but not their actual use.
[2] Other relevant regulatory systems include: Food Safety (Food Act 2014); Animal Welfare (Animal Welfare Act 1999); Biosecurity (Biosecurity Act 1993); international standards and Free Trade Agreements.
[3] These also regulate the use of some agricultural products depending on their properties.
[4] May be subject to change due to Gene Technology reform.

	Note that some of these groups are exempt from needing to register a trade name product.		
Review processes underway or planned	An independent review focussed on streamlining and efficiency. The review is intended to be completed by the end of 2024.* An existing operational forum of government officials (Ministry for the Environment, Ministry for Primary Industries, Environmental Protection Authority), representative bodies and inhibitor companies to understand regulatory pathways for greenhouse gas inhibitors.	An intended review to streamline approvals of hazardous substances, and subsequent changes to the HSNO regime following removal of the gene technology regulation. Initial advice on these topics is still being developed.	Comprehensive reform of gene technology regulations and creating a new biotechnology regulator. We understand initial policy decisions are to be considered by Cabinet in August to begin drafting the legislation

*Note: Processes/review on-hold while Ministry for Regulation undertakes current review.

NOTE

Ministry for Regulation

Minister and Portfolio:	**Hon David Seymour, Minister for Regulation** **Hon Andrew Hoggard, Minister for Food Safety** **Hon Penny Simmonds, Minister for the Environment**		
CC:	**Hon Judith Collins, Minister of Science, Innovation and Technology**		
Title:	**Next steps for the agricultural products regulatory review**	**Number**	**2024-053**
Date:	**14 June 2024**	**Security Level:**	**IN CONFIDENCE**

Purpose

Provide you with our current understanding of the review and what Ministers have agreed to, and the timelines for joint ministerial and Cabinet approval of the terms of reference.

Background

On Monday 10 June and Tuesday 11 June, the Minister for Regulation met individually with the Ministers for Food Safety and Environment, and the Minister of Science, Innovation and Technology, regarding a regulatory review into the approval path for agricultural products. Ministers agreed to the review, subject to this being separate (but complementary) to the Gene Technology reform program.

On 13 June, Ministers Seymour and Hoggard announced the review at Fieldays, and a joint press release also including Minister Simmonds was issued.

Details for the review

The Ministry for Regulation is working to the following understanding of the review and what ministers have agreed to:

Scope

- All agricultural products that are currently regulated under Agricultural Compounds and Veterinary Medicines (ACVM) and Hazardous Substances and New Organisms (HSNO), including those that involve genetic modification, are in scope.
- The design and operation of ACVM and HSNO is in scope.
- The design (and future operation) of Gene Technology is out of scope as this is subject to a separate process. The review is not intended to influence the Gene Technology reform program.
- The interfaces and any overlaps between the regulatory systems are also in scope.

Approach

- The review will be grounded in economic analysis, including considering:
  - the underpinning market failures and the basis for government intervention;
  - the costs and benefits of regulation (and the distribution of those); and
  - whether the regulations are working.
- The review will consider the system as a whole from the perspective of regulated parties.
- Analysis will be guided by issues encountered by regulated parties and regulators, rather than a comprehensive review of the systems.
- There will be relevant connections where necessary with the Gene Technology reform program and any other review or policy processes underway for ACVM and HSNO.

	• The Ministry for Regulation will produce a report on the review with findings and recommendations, which will be followed by a Cabinet paper seeking agreement to resulting action. *Roles* • The Ministers for Regulation, Food Safety and Environment will be joint ministers with shared decision making for the review. • Given the interface with the Gene Technology reform program, any advice will also be shared with the Minister of Science, Innovation and Technology. • The Ministry for Regulation will lead advice on the review, with input from the Ministry for Primary Industries, New Zealand Food Safety, Ministry for the Environment and Environmental Protection Authority. Input from the Ministry of Business, Innovation and Employment will also be sought where necessary. • Cabinet will approve the terms of reference for the review and the Government response following the final report. *Timelines* • The review is expected to be launched on 1 August, and completed by the end of 2024. These details will be refined, and added to, through cross-agency engagement during the development of the terms of reference, and will be subject to ministerial approval. We note that more specificity on the interface with the Gene Technology reform program will be needed, and the engagement approach will also need to be developed. s 9(2)(f)(iv)
Terms of reference and launch	To meet a launch date of 1 August for the review, the following timeline is proposed: • **13 June – 26 June**: draft Cabinet paper (including terms of reference) developed by agencies. • **26 June – 1 July**: Joint ministers consider and agree to the paper. • **2 July – 9 July**: Agency consultation on the paper (5 working days). • **10 July – 17 July**: Ministerial and coalition consultation on the paper (5 working days). • **18 July**: paper lodged for Cabinet consideration. • **23 July** (EXP) **or 24 July** (ECO): paper considered at Cabinet committee. • **29 July**: paper considered at Cabinet. As most Cabinet committees are not sitting earlier in July (due to the House being adjourned), there are few opportunities to have the paper considered sooner. The paper would need to be taken to CBC, either on 1 July (for 8 July consideration at Cabinet) or 15 July (for 22 July consideration at Cabinet), to achieve this.
Next steps	The Ministry for Regulation will work with agencies to develop the draft terms of reference and Cabinet paper for your consideration.
Author	Peter Clark, Principal Advisor, Sector Reviews
Manager	David Wansbrough, Sector Reviews Lead, Sector Reviews

Briefing Paper

2024-059

Ministry for Regulation

To	**Hon David Seymour, Minister for Regulation** **Hon Andrew Hoggard, Minister for Food Safety** **Hon Penny Simmonds, Minister for the Environment**		
Title	**Draft terms of reference and Cabinet paper for the Agricultural Products Regulatory Review**	Number	**2024-059**
Date	**24 June 2024**	Priority:	**High**
Action Sought	**Discuss** feedback on documents presented **Agree** to agency and stakeholder consultation	Due Date	**1 July 2024**
Contact Person	David Wansbrough, Sector Review Lead	Phone	s 9(2)(a)
Contact Person	Peter Clark, Principal Advisor	Phone	s 9(2)(a)
Attachments	Appendix A – draft Cabinet paper and terms of reference Appendix B – timeline options A3	Security Level	**IN CONFIDENCE**

Executive Summary

1. Based on our understanding of what Ministers have agreed, we have prepared a draft Cabinet paper and terms of reference for the regulatory review into the approval path for agricultural products (the review).
2. In addition to general feedback, there are several specific areas where we are seeking your views. This includes on how we define the end point of the approval path (and hence the scope of the review), the approach and composition of the proposed Sector Reference Group, and other Ministers to be involved.
3. With the intention for the review to be launched on 1 August and completed by the end of 2024, there are a few timeline options that could be considered. The principal trade-off is between a shorter time to decisions and action, with the extent of stakeholder engagement and the quality of analysis.
4. In addition to agency consultation on the draft Cabinet paper, we would also seek feedback through targeted stakeholder engagement on the terms of reference to understand their views. We have indicated the stakeholders we would engage with but are seeking your approval before doing so.
5. You are collectively meeting as Joint Ministers on 25 June to discuss the review. We suggest this is an opportunity for Ministers Hoggard and Simmonds to express their expectations for the review, to discuss the Cabinet paper and terms of reference, and to discuss ways of working through the review.

Recommended Action

We recommend that you:		***Minister for Regulation***	***Minister for Food Safety***	***Minister for the Environment***
a	**note** that, in addition to general feedback, specific feedback is sought on the end point of the approval path, the approach and composition of the proposed Sector Reference Group, and other Ministers to be involved;	*Noted*	*Noted*	*Noted*
b	**discuss** your feedback on the draft terms of reference, Cabinet paper and timeline options with the Ministry for Regulation review team;	*Agree / Disagree*	*Agree / Disagree*	*Agree / Disagree*
c	**agree** to the Ministry for Regulation beginning agency consultation on the draft Cabinet paper once your feedback has been addressed;	*Agree / Disagree*	*Agree / Disagree*	*Agree / Disagree*
d	**agree** to the Ministry for Regulation seeking feedback from targeted stakeholders on the draft terms of reference once your feedback has been addressed;	*Agree / Disagree*	*Agree / Disagree*	*Agree / Disagree*
Minister for Regulation alone:				
e	**agree** to refer this briefing to the Ministers of Science, Innovation and Technology and of Agriculture for their information.	*Agree / Disagree*		

s 9(2)(a)

Gráinne Moss
Acting Secretary for Regulation and Chief Executive
Ministry for Regulation
Date: 24 June 2024

Hon David Seymour
Minister for Regulation
Date:

Hon Andrew Hoggard
Minister for Food Safety
Date:

Hon Penny Simmonds
Minister for the Environment
Date:

Purpose of Report

6. Provide you with a draft Cabinet paper and terms of reference for the regulatory review into agricultural products (the review) for your feedback. Options for the timeline for the review have also been provided. This also seeks your agreement to the Ministry for Regulation starting agency and targeted stakeholder consultation on the terms of reference once your feedback has been addressed.

7. Prepares you for your joint meeting on Tuesday 25 June to discuss the review. A proposed agenda for this meeting has been provided.

Background

8. Through a series of bilateral meetings on 10 June and 11 June, you collectively agreed that the next regulatory review would consider the approval path for agricultural products. We understand you also agreed to be joint ministers for the purpose of the review.

9. On 14 June the Ministry for Regulation provided a note capturing our understanding of the review and what Ministers had agreed to, including a timetable for receiving Cabinet approval to the terms of reference of the review [2024-053].

10. The topic for the review was announced on 13 June at Fieldays, with a press release also issued by joint ministers.

Draft Cabinet paper and terms of reference

11. Please find attached for your consideration a draft Cabinet paper and terms of reference for the review [**Appendix A**]. These have been informed by our understanding of what Ministers had agreed to for the review, and also draws on the approach agreed for the Early Childhood Education Regulatory Sector Review where relevant.

12. We have engaged with and received feedback from the Ministry for Primary Industries, New Zealand Food Safety[1], the Ministry for the Environment, the Environmental Protection Authority, and the Ministry of Business, Innovation and Employment as part of this process. The Ministry for Regulation appreciates the efforts of partner agencies in providing responses in the short timeframes provided.

13. While all efforts have been made to finalise the documents for your consideration, there are some areas where further refinement of details will be necessary, including on the points raised in the following section.

14. There are several areas where we are seeking to test your views to inform the review. These include:

    a. **The end of the approval path**. As drafted, we are considering the review will focus on the path to market for products, ending at their registration so they can be used in the country. We are not intending to review regulations applying to the end users of the products, or the use on a particular property. This would mean that considerations under the Resource Management Act 1991 and the Health and Safety at Work Act 2015 would be out of scope for the review. Market access considerations managed through the Agricultural Compounds and Veterinary Medicines (ACVM) regulatory system would be in scope, but other market access considerations would not.

[1] New Zealand Food Safety is a business unit within the Ministry for Primary Industries.

b. **Sector Reference Group**. There are a range of options that could be considered for the approach to membership, and the breadth of stakeholders represented. Additional details around criteria and purpose for the Group will need to be reflected in the final terms of reference.

    i. **approach to defining membership**. This could be left to the industry representative groups to self-identify and agree, an existing body could be asked to identify them (e.g. the ACVM Advisory Council), or Government could appoint directly.

    ii. **Composition of the Group**. This could be: narrow to industry (including developers, users of agricultural products, processors and exporters); or could also include the wider stakeholder views relevant for the review and for which the regulatory systems seek to protect (including environmental stakeholders such as the Parliamentary Commissioner for the Environment, and those contributing Māori or human health viewpoints).

c. **Other Ministers for involvement**. The Minister of Agriculture, the Associate Minister of Agriculture (Horticulture) and the Minister of Health could be considered as having a direct role in the review (as a joint minister), or alternatively kept informed on progress.

15. *We are seeking your general feedback on these documents, and specific feedback on the identified areas, ahead of agency and proposed stakeholder engagement*.

Timeline options

16. We have also provided some timeline options for your consideration [**Appendix B**]. These all use an expected launch date of 1 August and are centred around the expectation that the review would be completed by the end of 2024.

17. The principal trade-off between the options is a shorter time to decisions and action, with the extent of stakeholder engagement and the quality of analysis. For the shorter timelines, there are also feasibility considerations for the Ministry for Regulation and partner agencies to be able to complete the review in the set time.

18. Ahead of receiving Ministerial feedback, the Cabinet paper and terms of reference are based on Option 1, which is the review teams' preferred option. This option seeks to balance time for meaningful engagement with stakeholders while ensuring the report stage of the review is completed in 2024.

19. *We are seeking your views on the timeline options presented.*

Consultation

20. As part of agency consultation on the review, and in alignment with the Cabinet Manual, we intend to seek feedback on both the Cabinet paper and terms of reference from:

    a. The Treasury, the Department of Prime Minister and Cabinet, Ministry of Business, Innovation and Employment, Ministry for Primary Industries, Ministry for the Environment, the Environmental Protection Authority, Ministry of Foreign Affairs and Trade, Conservation, Ministry of Justice, the Ministry of Health and WorkSafe.

21. As was done with the draft terms of reference for the Early Childhood Education Regulatory Sector Review, we would also seek feedback from targeted stakeholders on the draft terms of reference. This would include:

a. Those who have already engaged with the Regulation portfolio on the review, including Federated Farmers, Animal and Plant Health New Zealand, Agritech NZ, Horticulture New Zealand and DairyNZ;

b. Other key stakeholders, including Beef and Lamb New Zealand, the Meat Industry Association, Dairy Companies Association of New Zealand, the Veterinary Council of New Zealand, the Parliamentary Commissioner for the Environment, AgriZero and A Lighter Touch; and

c. Any additional stakeholders you identify.

22. *We are seeking your approval to start this engagement once you are satisfied your feedback has been addressed*.

Next steps for the Cabinet process

23. We propose the following timetable for completing the Cabinet process:

By 1 July	Joint Ministers' feedback received and addressed
2-9 July	Agency consultation and targeted sector consultation
10-17 July	Ministerial and coalition consultation starts
18 July	Lodging
23 July (EXP) or 24 July (ECO)	Cabinet Committee
29 July	Cabinet
1 August	Public announcements

24. If Ministerial feedback is addressed sooner than 1 July, the Ministry for Regulation will begin agency and targeted sector consultation earlier to provide them more time to respond.

Joint Ministers meeting on 25 June

25. You are collectively meeting on 25 June at 8:00pm-8:30pm in Minister Seymour's office. Members of the Ministry for Regulation review team and a representative from each agency are expected to be in attendance.

26. As way of an agenda, we suggest the following agenda items:

a. Opportunity for Ministers Hoggard and Simmonds to express their expectations for the review to the review team;

b. Discussion on the draft Cabinet paper and terms of reference, and the timeline options; and

c. Ways of working, including how Ministers prefer to be updated on the review, and at which points of the review you may seek to meet.

Next Steps

27. The review team will address any ministerial feedback received and provide updated versions to Ministers' offices as necessary to confirm the changes. We will then start agency and stakeholder consultation if agreed. A summary of agency and stakeholder feedback, in

addition to updated copies of the Cabinet paper and terms of reference, will be provided ahead of ministerial and coalition consultation.

28. The review team will also continue to progress planning for the review, recruitment and initial analysis.

Appendix A: Draft Cabinet paper and terms of reference

Appendix B: Timeline options A3

Timeline options for Agricultural Products Regulatory Review

Key notes:

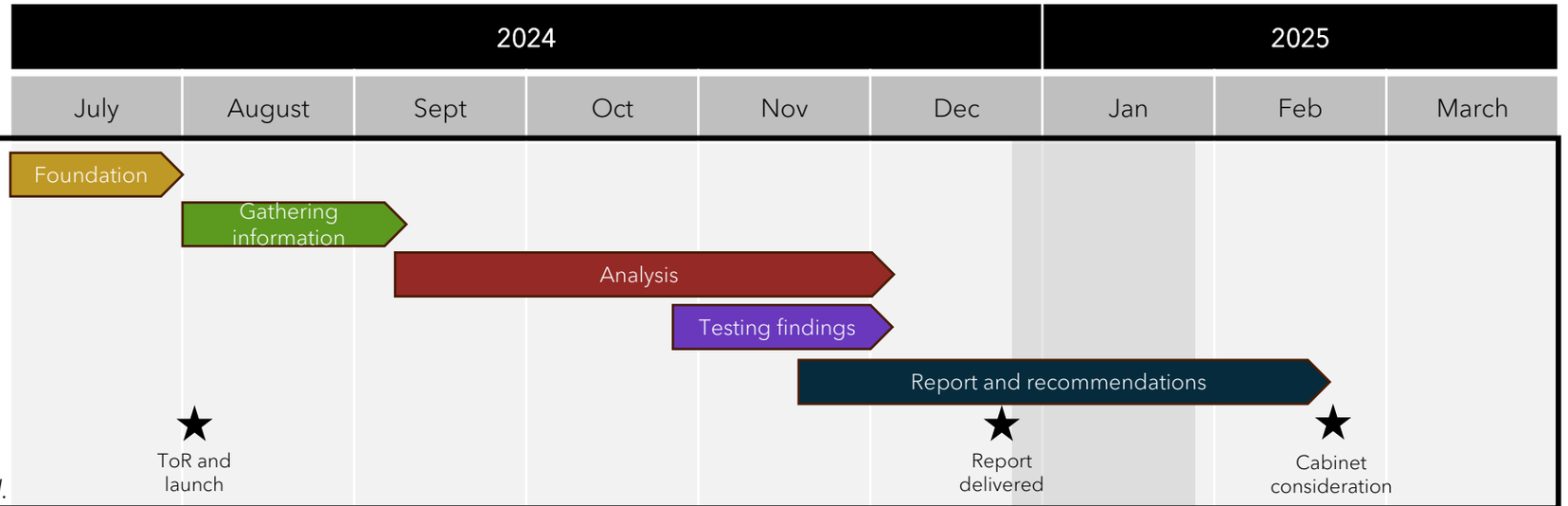
- The principal trade-off in options is between the time to completion of the review, with the amount of stakeholder engagement and the quality of the review.
- There is a notable feasibility risk for Option 2.
- Within Option 1, there is the potential to target these timelines but retain flexibility for delivery in 2025 in the case extended stakeholder engagement or analysis is required – the review team recommends this option.

Option 1. Report 2024, Cabinet 2025*

Pros:
- Enables some meaningful engagement with stakeholders on the findings.
- Ensures the review itself is completed in 2024.

Cons:
- Moderate feasibility risk
- Small delay to Cabinet decisions for action.

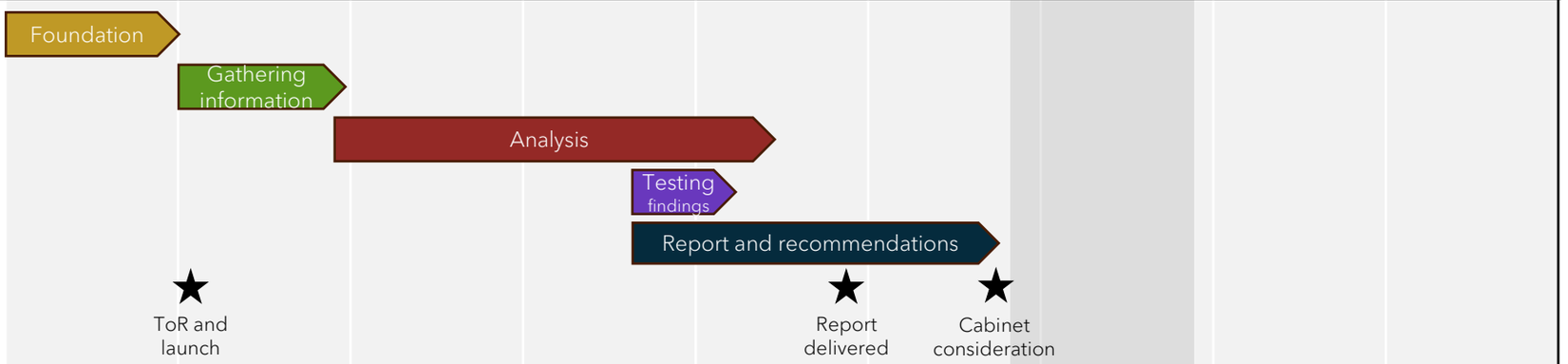
**Potential to target these timelines but retain flexibility if needed.*



Option 2. Report and Cabinet in 2024

Pros:
- Fastest time to Cabinet decisions for action.

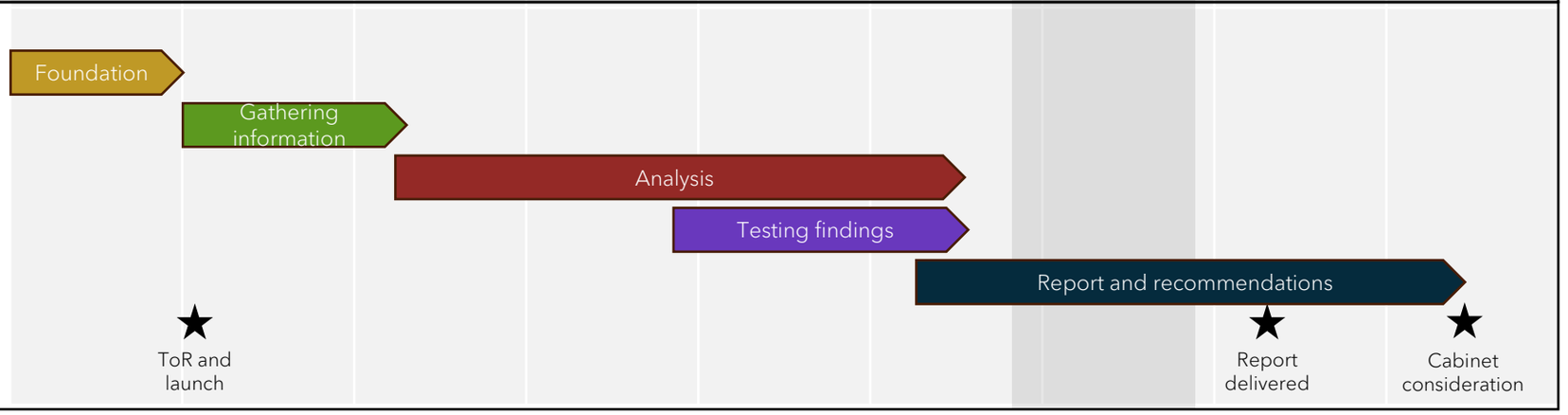
Cons:
- Very limited ability to test findings with stakeholders.
- Risk Cabinet Office delay to 2025 due to agenda capacity.
- Reduced depth or breadth of analysis.
- Large feasibility risk.



Option 3. Report and Cabinet in 2025

Pros:
- Allows greater testing with stakeholders (including ability to refine solutions).
- Enables greater depth and breadth of analysis.

Cons:
- Longest delay to Cabinet decisions for action.



Expected stages for the review

1. Foundation
a. Understanding of market failures and risks.
b. Desktop analysis of existing reports and reviews.

2. Gathering information
a. Stakeholder engagement on issues and opportunities with the current approval path.

3. Analysis
a. Unpack issues into contributing parts.
b. For each contributing part, assess against:
   a. the underpinning market failures, risks and the basis for government intervention;
   b. the costs and benefits (including distribution) of regulation;
   c. whether the regulations are working.
c. Identify solutions.

4. Testing findings
a. Testing analysis and potential solutions with an external reference group.

5. Report and recommendations
a. Summarise findings into final report.
b. Provide recommendations for action to Cabinet.

NOTE

Ministry for Regulation

Minister and Portfolio:	**Hon David Seymour, Minister for Regulation** **Hon Andrew Hoggard, Minister for Food Safety** **Hon Penny Simmonds, Minister for the Environment**		
Title:	**Summary of consultation feedback on the terms of reference and Cabinet paper for the Agricultural Products Regulatory Review**	**Number**	**2024-070**
Date:	**9 July 2024**	**Security Level:**	**IN CONFIDENCE**

Purpose

Provide you with an overview of stakeholder and agency feedback on the draft terms of reference for the Agricultural Products Regulatory Review (the Review), and how the Review Team has responded to that feedback.

Background

On 2 July, the Ministry for Regulation began seeking feedback from targeted stakeholders on the draft terms of reference for the Review. The stakeholders approached are set out in **Appendix A**, which also indicates whether feedback has been received yet. Agency consultation on the draft Cabinet paper and terms of reference was also started on 2 July. Both sets of groups were provided until 12pm on 9 July for returning feedback.

Stakeholder feedback

While many stakeholders have provided feedback, there are several who we have yet to receive a response from. The Parliamentary Commissioner for the Environment, who is the key environmental stakeholder consulted, will only be able to provide feedback by 11 July. The Review Team will provide an update on 11 July if there is any substantive late feedback received that should be brought to Ministers' attention.

Feedback received

Many stakeholders expressed support for the Review. Some noted that it traverses the main issues, while setting out a demanding but achievable timeframe.

The following stakeholder feedback **has been addressed**:

- while other regulatory systems are out of scope of the Review, any linkages or overlaps with ACVM or HSNO should be considered in scope;
- learnings from other domestic regulatory systems that are working well (including the Veterinarians Act 2005 and the Food Act 2014) should be considered;
- the different considerations that regulators must take into account when making decisions (as set out in the empowering Acts) should be considered; and
- the perspectives of researchers and developers of agricultural products should be explicit as a stakeholder view to consider.

The Review Team **agrees but does not feel changes are necessary** for the following feedback:

- a range of specific considerations for analysis, including undertaking cost-benefit analysis, funding models, international alignment opportunities and regulator efficiency – this is being noted to inform planning for the analysis; and
- variations to existing approvals should be considered – this is intended to be in scope.

	The following feedback **has not been responded to** (with rationale): • strategic principles for the Review should be set out – these will be considered as part of the Review, but do not need to be set out in the terms of reference; • the Review should consider futureproofing against risks relating to new and emerging technologies – other functions of the regulators, including monitoring and horizon-scanning, is out of scope for the Review, and our immediate focus is on current issues faced by regulated parties; and • the approval path for agricultural products intended solely for export should be considered, rather than focusing only on those for domestic use – our view is the most pressing issue is to address access for New Zealand farmers and growers in the first instance. As the Sector Reference Group has been identified by ministerial appointment, we are **seeking your views before making any amendments** in response to the following feedback: • the inclusion of an independent chair and governance members from wider industries; • defining skills criteria for the members (e.g. strategic, systems thinking, governance and leadership requirements); and • other stakeholders requesting being part of the industry engagement and/or Sector Reference Group (including Zespri, Beef and Lamb New Zealand, DairyNZ).
Agency feedback	Agency feedback was aligned with the view expressed by stakeholders. The following additional feedback from agencies **has been addressed**: • clarifying that any change in scope of the review would not include the regulation of gene technology; • signalling that, given the complexity of the regulation and the significant health and trade implications, timelines may need to be flexible to ensure the Review is done well; • adding material on how recommendations with implications broader than the scope of the Review will be approached; and • adding more prominence to the senior leaders group from across agencies that will support the Review Team. The following feedback **has not been responded to** (with rationale): • engaging with health and food safety workers, and ensuring consideration for impacts on antimicrobial resistance – this may be considered by the Review but does not need to be specified in the terms of reference; • acknowledging the role of vertebrate pesticides in predator control programmes – this is outside of the scope of the Review; and • that representatives from the Meat Industry Association, the Fertiliser Association, and/or the biodiversity and biosecurity industry be included as part of the Sector Reference Group – this is a decision for Joint Ministers.
Next steps	Updated copies of the Cabinet paper and terms of reference are attached at **Appendix B**. The Review Team will make further changes to these as requested ahead of Ministerial and Coalition consultation beginning on 10 July.

	We understand the Minister for Regulation's office will lead ministerial and coalition consultation on the Cabinet paper. This is expected to be undertaken between 10 and 17 July to meet the expectation for five working days being provided for this [Cabinet Office circular CO (24) 2]. To meet a launch date of 1 August for the review, the forward timeline is: • **18 July**: paper lodged for Cabinet consideration. • **23 July:** paper considered at EXP Cabinet committee. • **29 July**: paper considered at Cabinet. If necessary, the Review Team will also provide an update on 11 July if there is any substantive late feedback that should be brought to Ministers' attention.
Author	Peter Clark, Agricultural Products Regulatory Review Lead
Manager	Bryan Wilson, Acting Sector Reviews Lead

Appendix A: Stakeholders and agencies consulted

Stakeholders

Organisation	**Response**
Federated Farmers	Yes
Animal and Plant Health New Zealand (APHNZ)	Yes
Horticulture New Zealand	No
Dairy Companies Association of New Zealand (DCANZ)	Yes
Veterinary Council of New Zealand	No
New Zealand Veterinary Association	Yes
Foundation for Arable Research	No
Zespri	Yes
New Zealand Wine Growers	No
Agritech NZ	No
Dairy NZ	Yes
Beef and Lamb New Zealand	Yes
Meat Industry Association	No
Parliamentary Commission for the Environment	Expected 11 July
AgriZero NZ	Yes
New Zealand Agricultural Greenhouse Gas Research Centre	Yes
A Lighter Touch	Yes
Fonterra	No
Silver Fern Farms	No
Apiculture NZ	No
Bayer	No
DSM	No

Agencies

Organisation	**Response**
Environmental Protection Agency	Yes
Ministry for Primary Industries / New Zealand Food Safety	Yes
Ministry for the Environment	Yes
Ministry of Business, Innovation and Employment	Yes
The Treasury	Yes
Ministry of Health / National Public Health Service (Health NZ)	Yes
WorkSafe	No
Ministry of Foreign Affairs and Trade	No *
Department of Conservation	Yes
Department of the Prime Minister and Cabinet (DPMC)	Yes
Ministry of Justice	Yes

*__Note__ for proactive release: the Ministry for Foreign Affairs and Trade had provided a response

Appendix B: Updated draft Cabinet paper

NOTE

Ministry for Regulation

Minister and Portfolio:	**Hon David Seymour, Minister for Regulation**		
Title:	**Talking points on Agricultural and Horticultural Products Regulatory Review for EXP**	**Number**	**MFR2024-076**
Date:	**18 July 2024**	**Security Level:**	**UNCLASSIFIED**

Purpose	Provide you with talking points on the Agricultural and Horticultural Products Regulatory Review to support your attendance at EXP.
Date of meeting	23 July 2024
Background	• You are taking a paper to the Expenditure and Regulatory Review Committee on 23 July and to Cabinet on 29 July to seek agreement to the terms of reference for the Agricultural and Horticultural Products Regulatory Review. • Consultation with agencies and targeted stakeholders was undertaken from 2 July through 9 July and ministerial and coalition consultation was undertaken from 10 July to 17 July. Some of the feedback received was addressed in the version provided to Cabinet [2024-070].
Talking points	• Access to agricultural and horticultural products is important to support primary sector productivity and provide protection against pests and disease. New products may also have improved environmental benefits, involving softer chemicals. • Farmers and growers have regularly talked of how long, difficult and complex it is to get new products approved in New Zealand. • This review will ensure that the approval path for these products is appropriately balancing access with managing risks to human health, trade, the environment and animal welfare. • The review will consider the basis for government intervention, the costs and benefits of the regulatory approach, and how well the regulations are working. • The Ministers for Food Safety and the Environment agree with the need for this review and will jointly oversee the work. • Because the review may have implications for other portfolios, we will keep key ministers informed as the review progresses. • There has been initial engagement with the primary sector on the draft terms of reference, and they have been very supportive of the review as proposed. • Throughout the review, there is a need to be mindful of how regulation of agricultural and horticultural products relates to trade and the importance of maintaining New Zealand's reputation as a trusted trade partner. • The review is expected to be completed in 6-months, but this is a complex and important area of regulation so some flexibility may be required. Joint Ministers are seeking to return to Cabinet in the first quarter or 2025 for decisions.

Next steps	We recommend sharing these talking points with Ministers Hoggard and Simmonds ahead of the Committee meeting on 23 July.
Author	Maria Spencer, Senior Advisor
Manager	David Wansbrough, Sector Reviews Lead

Office of the Minister for Regulation

Office of the Minister for Food Safety

Office of the Minister for the Environment

Cabinet Expenditure and Regulatory Review Committee

Terms of reference for the approval path for agricultural and horticultural products regulatory review

Proposal

1 This paper seeks agreement for the Ministry for Regulation to undertake a regulatory review into the approval path for agricultural and horticultural products. The proposed terms of reference for the review are attached at Appendix 1.

Relation to government priorities

2 The Coalition Agreement between the National and ACT Parties committed to carrying out regulatory sector reviews in consultation with the relevant ministers. The Primary Industries were identified as a potential sector for review. More broadly, the Agreement also included a commitment to reduce farming regulation.

Background

3 The Ministry for Regulation was established on 1 March 2024 as a central agency, with one of its functions to carry out regulatory sector reviews. The reviews will assess whether regulations are achieving appropriate outcomes for a particular sector and recommend where unnecessary rules and regulations could be removed, or where different regulatory approaches would better achieve the Government's objectives. The first regulatory review into early childhood education was launched on 5 June 2024 [SOU-24-MIN-0050].

Review of the approval path for agricultural and horticultural products

4 Farmers and growers use a range of different agricultural and horticultural products in their businesses, including feeds, fertilisers, veterinary medicines, pesticides and environmental inhibitors. These support horticultural and farming productivity, boost our agricultural and horticultural exports, and help protect against pests. Timely access to newer and improved products is important to maintain our competitiveness and to stay ahead of any developing resistance in pests.

5 New agricultural and horticultural products can pose both opportunities and a range of risks, including some that are unique to our environment and primary production systems. Risks include residues in food that could have impacts to human or animal health, our considerable trade in agricultural and horticultural exports and market access, or have long term impacts on the environment. To manage these risks, agricultural products are approved under the Agricultural

Compounds and Veterinary Medicines (ACVM) Act 1997, and, if the products are hazardous substances or new organisms, they also require approval under the Hazardous Substances and New Organisms (HSNO) Act 1996. The HSNO regulatory system also regulates a broader range of substances and organisms that are not agricultural products.

6 We are hearing that the approval process for agricultural and horticultural products is overly complex, costly, and time consuming. This means New Zealand's farmers and growers may not have timely access to products designed to maintain productivity and agricultural security, prevent and treat disease and illness of livestock, manage pests, or to reduce their environmental footprint.

7 Timely access to new products is important, as these may have improved environmental benefits or involve softer chemicals. Simple, clear, and essential rules and regulations that protect New Zealanders, their economy, and their environment without creating unnecessary market barriers will help them to do more – leading to greater productivity and better outcomes for all of us.

8 The next regulatory review will consider the approval path for agricultural and horticultural products, to ensure they are appropriately balancing access and managing risk to enable our primary sector to succeed and thrive.

Scope and approach to the regulatory review

9 The review will consider the ACVM and HSNO regulatory systems as they relate to the assessment and approval for agricultural and horticultural products. The approval path will be considered as starting from information collection for applications through to receiving approval for domestic use. The review will consider any conditions attached to approval of products.

10 All agricultural and horticultural products that are currently regulated under the ACVM regulatory system, including those that are also regulated under the HSNO regulatory system, are in scope. Any products that are only regulated under the HSNO regulatory system will not be in scope of the review. Other regulatory systems are also out of scope, but any linkages or overlaps with the ACVM and HSNO regulatory systems may be considered.

11 Reassessment processes will also be considered as part of the review, alongside the primary focus on the assessment and approval path. Outside of these, the wider functions of the regulators, including monitoring, compliance and enforcement, will not be considered.

12 The review will look at both regulatory design and regulatory practice, and the interface and overlap between regulatory systems. In assessing each of these parts, the following questions will be explored:

12.1 what are the underpinning market failures and the basis for government intervention;

12.2 what are the costs and benefits of regulation, and the distribution of those across different parties; and

12.3 how the regulations are working, including compared to equivalent regimes in other countries.

13 The review will draw on existing domestic and international reports and reviews. Comparison with approaches taken by international counterparts will be an important feature of the review.

14 A range of stakeholder views will need be considered. This includes those who are trying to bring products to market, New Zealand farmers and growers, processing and exporting companies, international supply chains, overseas regulators, public health and the environment. The HSNO Act 1996 also requires consideration for impacts on Māori and their culture and traditions.

15 The regulation of gene technology is out of scope for the review. We expect our review to sit alongside and complement work in this area, in addition to any other reviews underway for the two regulatory systems. This includes the work the Ministry for the Environment are already leading on investigating potential improvements to the assessment and approval of hazardous substances under the HSNO Act 1996.

16 Implementation of recommendations will be a separate but linked process. In general, we expect the recommendations to be considered by Cabinet after the review has been completed and with sufficient analysis of implications, including costs and resourcing. There may be some opportunities, where relevant Ministers or agencies have the existing authority, for changes to be made as the review continues. Whether this is feasible will depend on the nature of the changes proposed.

Roles and responsibilities

17 We will have joint oversight and decision-making for the review, ensuring that the review delivers to our expectations. We will ensure that other interested Ministers, including the Minister of Science, Innovation and Technology, the Minister for Trade/Minister of Agriculture, the Associate Minister for Agriculture (Horticulture), and the Minister of Health are kept informed on the progress of the review.

18 The review has a narrow scope, but we are mindful the review may identify wider contributors to issues with the approval path for products. To prepare for this scenario, we are seeking authorisation to amend the scope of the review, if necessary. Any changes would be limited to the bounds of the ACVM and HSNO regulatory systems, and not include the regulation of gene technology. Changes to the scope may have implications for the intended timing of completion of the review.

19 The review will be led by the Ministry for Regulation within its central government agency mandate to strengthen the regulatory management

system and improve regulatory quality. The Ministry for Primary Industries, New Zealand Food Safety, the Ministry for the Environment, and the Environmental Protection Authority will be closely engaged throughout the review. A group of senior government officials from these agencies will provide support to the Review Team. Other agencies will be engaged where appropriate.

Stakeholder engagement

20 Industry representative groups and businesses will be the primary means to contribute many of the stakeholder views to the review. In addition to direct engagement early in the review with a range of organisations, a Sector Reference Group will be used to test findings, analysis and potential solutions later in the review. We will ask specific organisations, which collectively cover the breadth of industry views, to nominate a member with the appropriate technical expertise to be a part of the Group.

21 Targeted engagement with some selected stakeholders will also be needed to ensure remaining views are captured. This will include with those who can bring an understanding of the cultural perspectives and potential impacts on Māori, environmental impacts, public health, R&D perspectives, and international regulators. There will be bespoke engagement with these stakeholders at key points of the review.

Timeline for the review

22 There is a pressing need for timely access to agricultural and horticultural products, and so we are setting an ambitious timeline for the review. We expect the Review Team to provide an initial report back to us before the end of the year. Following the report, we seek an invitation to return to Cabinet in early 2025 with recommendations that seek commitment to actions that will help our farmers and growers get timely access to the products they need.

23 We are mindful this is a complex area of regulation, and it is important that the review is done well given the health and trade implications. These timelines may need to be flexible if there is good reason to take more time.

Cost-of-living Implications

24 The availability of safe and affordable food is important to New Zealand and its trade partners. The review is expected to identify opportunities to reduce regulatory compliance costs for the manufacturers and producers of agricultural and horticultural products while ensuring risks are managed.

Financial Implications

25 The activities undertaken by the Ministry for Regulation as part of the review will be funded through baseline funding. The engagement by other agencies in the review will be funded from their own baseline.

Use of external Resources

26 No consultants or contractors have been involved in the review to date.

Legislative Implications

27 This proposal has no direct legislative implications; however, the review could recommend changes to both primary and secondary legislation. The detail of any recommended changes will be considered by Cabinet as part of the response to the review.

Impact Analysis

Regulatory Impact Statement

28 This paper does not seek agreement to regulatory proposals at this stage, and therefore Cabinet's impact analysis requirements do not apply. It is expected that the review will identify opportunities to improve the quality of the ACVM and HSNO regulatory systems, ensuring that regulatory decisions are based on principles of good law-making and economic efficiency.

Climate Implications of Policy Assessment

29 The Climate Implications of Policy Assessment team has been consulted and confirms that the requirements do not apply to this proposal, as the threshold for significance is not met.

Population Implications

30 The review will assess regulatory systems that manage risks to public health, agricultural security, and the health and safety of people who may be exposed to the regulated compounds. The effective functioning of these regulatory systems will help protect the health and safety of agricultural workers and domestic and international consumers. As the review progresses, it will be mindful of the New Zealand Government's obligations under domestic and international law.

Human Rights

31 New Zealand is party to the International Covenant on Economic, Social and Cultural Rights, which recognises the fundamental right of everyone to be free from hunger. This includes a commitment to take measures to improve methods of production of food by making full use of technical and scientific knowledge and by developing or reforming agrarian systems in such a way as to achieve the most efficient development and utilization of natural resources.

Consultation

32 The following departments and agencies were consulted on this paper: the Treasury, the Ministry for Primary Industries, the Ministry for the Environment, the Environmental Protection Authority, the Ministry of Business, Innovation

and Employment, the Ministry of Health, WorkSafe, the Ministry of Foreign Affairs and Trade, and the Department of Conservation. The Department of Prime Minister and Cabinet has been informed.

33 Feedback was sought from the following stakeholders on the draft terms of reference alone: Federated Farmers, Animal and Plant Health New Zealand, Horticulture New Zealand, Dairy Companies Association of New Zealand, Veterinary Council of New Zealand, Foundation for Arable Research, Zespri, New Zealand Wine Growers, AgritechNZ, DairyNZ, Beef and Lamb New Zealand, Meat Industry Association, Parliamentary Commissioner for the Environment, AgrizeroNZ, New Zealand Agricultural Greenhouse Gas Research Centre, A Lighter Touch, Fonterra, Alliance Group, Silver Fern Farms, Apiculture NZ, New Zealand Veterinary Association, Bayer, DSM.

Communications

34 We announced the subject of the review on 13 June 2024, and we intend to publicly launch the review on 1 August 2024. The review has already generated some media, and there is likely to be more media coverage as the review starts and seeks feedback.

Proactive Release

35 We intend to proactively release this Cabinet paper once decisions have been made subject to redactions as appropriate under the Official Information Act 1982.

Recommendations

The Ministers for Regulation, Food Safety and the Environment recommend that the Committee:

1 agree to the terms of reference for the regulatory review (the review) into the approval path for agricultural and horticultural products attached at Appendix 1;

2 agree to the launch of the review;

3 authorise the Ministers for Regulation, Food Safety and the Environment to amend the scope of the review if necessary, provided this remains within the Agricultural Compounds and Veterinary Medicines and Hazardous Substances and New Organisms regulatory systems, and does not include the regulation of gene technology; and

4 invite us to report back to Cabinet to seek decisions in Quarter 1 of 2025 following the completion of the review.

Hon David Seymour

Minister for Regulation

Hon Andrew Hoggard

Minister for Food Safety

Hon Penny Simmonds

Minister for the Environment

Appendix 1: Terms of Reference for the regulatory review of the approval path for agricultural and horticultural products

Terms of Reference for the agricultural and horticultural products regulatory review

Purpose

The regulatory review into the approval path for agricultural and horticultural products (the review) will focus on the approvals needed for any products used to manage plants and animals under the Agricultural Compounds and Veterinary Medicines (ACVM) and Hazardous Substances and New Organisms (HSNO) regulatory systems.

The review seeks 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, including to human health, trade, animal welfare, agricultural security, and the environment.

The review will aim to achieve this in part through:

- looking at the individual regulatory systems as a whole from the viewpoint of those trying to seek approval through them;
- understanding what is the problem being addressed by the regulation and whether the regulatory systems are achieving their stated purpose within the context of this review;
- grounding the review in economic analysis of the market and regulatory interventions, including consideration of the underpinning market failures and the costs and benefits of regulation;
- benchmarking our approval path against comparable international regulators and international best practice; and
- considering how the overlap and interface between the HSNO and ACVM regulatory systems is managed by government agencies.

Background

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 per cent of all merchandise exports. Dairy products represent close to half of these exports. In addition to the direct contribution to the economy, the agriculture sector is also a significant employer, not only across rural and regional New Zealand, but also in major urban areas.

Farmers and growers use a range of different products as part of running their businesses. This includes access to pesticides (which include herbicides, insecticides, fungicides and vertebrate toxin agents) to manage and control pests, and inhibitors to reduce the environmental footprint of their operations. This also includes access to feed for their animals, fertilisers to add nutrients to their soils, and veterinary medicines to prevent or treat disease and illness of livestock. Access

to environmental inhibitors is critical to maintain access to markets and meet expectations of consumers.

Timely access to new products is important. This can help maintain competitiveness for our farmers and growers, both with international competitors who may already have access to the products, and to keep up with changing consumer expectations and the requirements of trading partners. Access to agricultural and horticultural products can also help maintain or increase productivity and agricultural security, as existing products become less effective or as pests develop resistance to existing chemicals. Newer products may also have less impact on animal or plant health, human health, and the environment than those currently in use.

However, new agricultural and horticultural products can pose risks to a range of different groups and New Zealand's wider trade interests. There is a need to ensure that:

- food that has been produced with them is safe for domestic and international consumers to eat, and that they are safe for horticultural and farm workers to work with;
- international supply chains are confident that New Zealand primary products are safe to eat, and international regulators are confident in how risks are being managed and that New Zealand meets their market access requirements;
- animal welfare and productivity are not compromised through the use of the agricultural and horticultural products;
- agricultural and horticultural products are not impacting the long-term health of our farms and orchards; and
- the use of agricultural and horticultural products doesn't adversely affect human health or the environment.

Because information about these potential impacts may not be immediately obvious or available to those who wish to use them, and more generally the risks to the public interest, the Government has adopted a regulatory approach to manage access to agricultural and horticultural products. This approach is similar to that adopted by our major trade partners, such as Australia, the European Union, the United States of America and Canada, among others. In New Zealand this access is regulated by the ACVM and HSNO regulatory systems.

Scope

Broadly, the review will assess the approval path for agricultural and horticultural products in New Zealand. Within this, we will consider the following:

- all **agricultural and horticultural products** that are currently regulated under the ACVM regulatory system, including those that are also regulated under the HSNO regulatory system, are in scope.
- the assessment and approval process (**approval path**), starting with information collection for applications and ending at approval for domestic use of the product. This includes any conditions attached to the approval of agricultural and horticultural products.
- the review will also consider **reassessment** processes, including the thresholds for triggering reassessments.

- the review will focus on the **ACVM regulatory system** and the **HSNO regulatory system** as they relate to the assessment and approval of agricultural and horticultural products, and may include considering any linkages or overlaps with other regulatory systems.
- In assessing the regulatory systems, the review will seek to understand:
    - the relevant **public interest matters**, including market failures, risk thresholds and the basis for government intervention;
    - the **costs and benefits of the regulation** (and the distribution of those across different parties); and
    - **how well the regulations are working** to achieve their intended purpose, including when benchmarked against comparable international regulators.
- The review will look at:
    - **regulatory design**, including how the regulatory systems have been setup, and the legislation, notices, and other rules that apply;
    - **regulatory practice**, including the practices and behaviours of the agencies that carry out the range of functions within a regulatory system as it relates to product approval; and
    - the **interface**, both legislative and operational, between the ACVM and HSNO regulatory systems, including any overlaps or duplication between them.
- As part of **assessing the approval path**, the Review may consider the quality and quantity of information that needs to be provided by applicants, the models that are used to inform decision-making, and how regulators are performing. Where empowered by legislation, the use of group standards and recognition of international regulators may be reviewed, and which principles of the empowering Act are considered at which stages of an assessment. The value of approval, and ensuring that secondary legislation is not broader than provided for by the primary legislation, may also be considered. The different considerations in decision-making, as set out in the empowering Acts, may be reviewed, and learnings from other domestic regulatory systems may be considered.
- While the review will look at the systems primarily from the viewpoint of those trying to navigate them, a **range of stakeholder views** will be considered as part of analysis. This includes those who seek to bring products to market (regulated parties), New Zealand farmers and growers who seek to use them, those companies processing and exporting primary products internationally, international supply chains for our agricultural and horticultural exports, overseas regulators, R&D perspectives, Māori, public health and the environment.
- The review will deliver a **report for Joint Ministers and a paper for Cabinet consideration of the recommendations**. Implementation will be a separate but linked process [more detail in later section].

Out of scope

The review will not consider:

- the regulation of gene technology as part of HSNO, as this is subject to a separate process;

- products only regulated under HSNO are not in scope of the review;
- regulation that is not directly covered by the ACVM and HSNO regulatory systems (including regulation under the Health and Safety at Work, Customs, Transport, Resource Management, Animal Welfare, Fair Trading and Biosecurity regulatory systems), although any linkages or overlaps with the ACVM and HSNO regulatory systems may be considered;
- individual applications or complaints, or the actions of individual staff members of the regulators;
- other functions of the regulatory system, including monitoring and evaluation (except for that related to reassessment), compliance and enforcement, and standard setting; and
- the funding levels of regulators, although the distribution of costs and benefits for operating the regulatory systems may be considered as part of cost benefit analysis.

Roles

Ministers

Collectively the Ministers for Regulation, Food Safety and the Environment will have oversight and decision-making for the review. To be clear, this review does not affect the existing responsibility and decision-making the Minister for Food Safety has for ACVM, and the Minister for the Environment has for HSNO.

Other relevant ministers, including the Minister of Science, Innovation and Technology, the Minister of Agriculture, the Associate Minister for Agriculture (Horticulture), and the Minister of Health will be informed and engaged as necessary on the review.

Cabinet will approve the terms of reference for the review and will be the main forum for agreeing the Government response to the recommendations from the report. Joint Ministers will have authority to amend the scope of the review, if necessary, within some bounds set by Cabinet.

Agencies

The review will be led by the Ministry for Regulation within its central agency mandate to strengthen the regulatory management system and improve regulatory quality. While the review will be undertaken with cross-agency and stakeholder input, the Ministry for Regulation retains its independence and the ability to make comments and recommendations that may not be fully supported by other agencies or stakeholders. In saying this, the Ministry for Regulation recognises that change is more likely to succeed and be enduring where there is consensus.

The Ministry for Primary Industries, New Zealand Food Safety, the Ministry for the Environment and the Environmental Protection Authority will work closely with the Ministry for Regulation and provide information and advice on the regulatory systems they play a role in and are responsible for. A group of senior government officials from these agencies will provide support to the Review Team. Other agencies, including the Ministry for Business, Innovation and Employment, WorkSafe and the Ministry of Health, will be engaged where appropriate.

Industry

Industry representative groups and some businesses will be the primary means to contribute many of the stakeholder views to the review. This includes the views of those seeking to bring

products to market, New Zealand farmers and growers, processors and exporters, and the views of their international supply chains.

In addition to broad engagement with these groups early in the review, the review team will call on a Sector Reference Group to test back their findings, analysis and options. The Group would be advisory in nature, without decision-making powers. To cover the breadth of industry views, we are asking for the following organisations to nominate a member with the appropriate technical expertise to be a part of the Group:

- Horticulture New Zealand;
- New Zealand Winegrowers;
- Foundation for Arable Research;
- Dairy Companies Association of New Zealand;
- Animal and Plant Health New Zealand;
- Veterinary Council of New Zealand; and
- Federated Farmers.

Acknowledging that industry representative groups and businesses do not represent the full range of stakeholder voices, further information is provided in the engagement section on how broader stakeholders will have an opportunity to contribute to the review.

Review procedure

Approach

The review will be undertaken in several stages, with some of these overlapping. Engagement with government agencies will be undertaken across all stages.

1. **Foundation**
    - Understanding of the relevant public interest matters, including market failures, risk threshold and government intervention.
    - Desktop analysis of relevant existing reports and reviews, both domestic and international.
2. **Gathering information**
    - Engage with stakeholders to identify issues and opportunities with the current approval path, and what relevant information they can contribute for the review.
3. **Analysis**
    - Assess what we've heard from stakeholder engagement and desktop review.
    - Unpack issues into the different parts that contribute to them.
    - For each part, assess against:
        - the underpinning public interest matters, including market failures, risk thresholds and the basis for government intervention;
        - the costs and benefits (including their distribution) of regulation; and
        - whether the regulations are working.
    - Identify, develop and assess options that will address these issues, both in the short term and longer term.

4. **Testing findings**
    - Test back analysis and potential solutions with the Sector Reference Group, and selected additional stakeholders as necessary.
5. **Report and recommendations**
    - Summarise findings, including what we have heard from stakeholders, and options into a final report for Joint Ministers.
    - Provide recommendations for Joint Ministers to take to Cabinet to seek agreement to action.

Engagement

Industry representative groups and businesses

Industry representative groups and businesses will be the primary means to contribute many of the stakeholder views to the review. This engagement will take two main forms:

- **Initial engagement with the industry representative groups and businesses**. This will provide an opportunity for the groups to identify issues and opportunities with the current regulatory path, and to identify evidence to support the review. This is likely to include a mixture of online town-hall meetings and written submissions.
- **Targeted engagement with Sector Reference Group**. This will involve closer engagement with a representative group of external stakeholders to test findings. This is likely to include a series of online engagements.

Other stakeholder interests

Acknowledging that industry representative groups do not represent all the stakeholder views relevant for the review, there will also be targeted engagement with some selected stakeholders. These stakeholders will include those who can bring an understanding of:

- cultural perspectives and potential impacts on Māori, noting that these considerations are a part of the principles relevant to the purpose of the HSNO Act;
- public health;
- the impact that agricultural and horticultural products can have on the environment;
- R&D considerations for the development of new products; and
- the importance of appropriately managing agricultural and horticultural products use to safeguard New Zealand's official assurances and trade for primary products, which may include international regulators or standards bodies.

This engagement will likely be through a mixture of online and/or in person engagements, in addition to written submissions.

Reporting and oversight

The review team will report to Joint Ministers (Ministers for Regulation, Food Safety, and the Environment) throughout the review, and the review report will be provided to them. Additional oversight will be provided by group of senior leaders from across the Ministry for Regulation, Ministry for Primary Industries, New Zealand Food Safety, Ministry for the Environment, and the Environmental Protection Authority.

Connections

With implementation activities

Any recommendations identified through the review will need to be agreed to by relevant minsters, agency decision-makers or Cabinet, and made with sufficient analysis of implications including costs and resourcing. Some recommendations may be able to be agreed to by relevant ministers or agency decision-makers without the need for, and ahead of, consideration by Cabinet. In contrast, some recommendations, especially where they have implications broader than the scope of the Review, may require further advice from the relevant agency before Cabinet takes decisions on these. The Ministry for Regulation will work closely with the relevant agencies that are seeking agreement to actions ahead of consideration by Cabinet and will support advice in parallel with its review work where appropriate.

Progressing recommendations may involve several different mechanisms, each of which will have set processes and varied timeframes. The Ministry for Regulation will work closely with and support other agencies seeking to make improvements as quickly as possible and will support actions in parallel with its review work where appropriate.

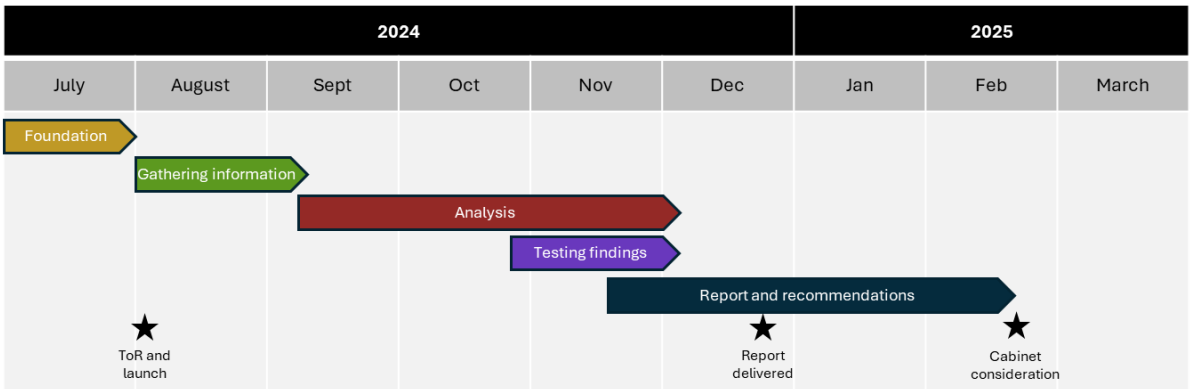
With related processes

There may be a range of actual or planned processes (including reviews or reform) in parallel to the review that relate to ACVM or HSNO, or that touch on the purpose of this review. In each instance, the review team will meet with the relevant organisations to understand the interface between the work, any opportunities for alignment, and an engagement approach to ensure ongoing connection where relevant.

Timing and milestones

The review is expected to be launched in early August, with a report (final, or preliminary) delivered to Joint Ministers by the end of 2024. It is expected that Cabinet will consider the recommendations from the review in the first quarter of 2025.

The estimated timing of the different phases of the review are indicated in the following figure.



Background

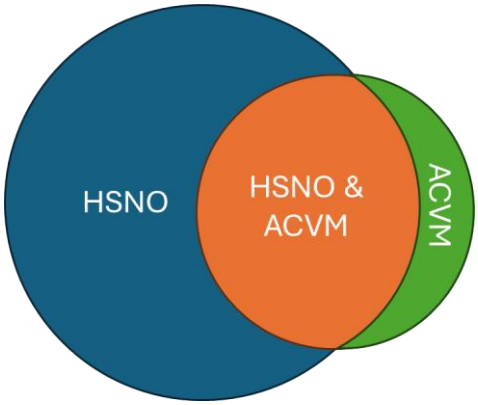
Regulatory systems relevant to assessment and approval of products

There are two regulatory systems that are most relevant to the assessment and approval of products for use in agriculture. These are the Agricultural Compounds and Veterinary Medicines (ACVM) regulatory system, and the Hazardous Substances and New Organisms (HSNO) regulatory system.

Regulatory system	**Agricultural Compounds and Veterinary Medicines**	**Hazardous Substances and New Organisms**
Legislation	Agricultural Compounds and Veterinary Medicines Act 1997	Hazardous Substances and New Organisms Act 1996
Regulator	New Zealand Food Safety (Business Unit within Ministry for Primary Industries)	Environmental Protection Authority
Policy agency	Ministry for Primary Industries	Ministry for the Environment
Responsible Minister	Minister for Food Safety	Minister for the Environment
Purpose	Prevent or manage risks associated with the use of agricultural compounds, being— • risks to public health; and • risks to trade in primary produce; and • risks to animal welfare; and • risks to agricultural security. Ensure that the use of agricultural compounds does not result in breaches of domestic food residue standards. Ensure the provision of sufficient consumer information about agricultural compounds.	Protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms[4].
Regulated parties	Anyone seeking to import, manufacture, sell or use agricultural compounds or veterinary medicines.	Anyone who imports or manufactures a hazardous substance. Anyone who imports, develops, field tests or releases a new organism.
Regulated products	Substances used to help manage plants and animals, including: • veterinary medicines (substances used for animals, including companion animals) • agricultural chemicals (substances used for plants, including herbicides, fungicides, insecticides, plant growth regulators, surfactants, and adjuvants) • vertebrate toxic agents (substances that kill or limit the viability of animals, such as possums, rodents, and other unwanted mammals) • fertilisers, plant biostimulants, and soil conditioners • pet food and animal feed (including dietary supplements)	All products, chemicals or mixture of chemicals that has one or more of the following properties: • explosive; • flammable; • oxidising; • toxic; • corrosive; • ecotoxic. This includes agricultural chemicals, veterinary medicines, vertebrate toxic agents, fertilisers, environmental inhibitors, industrials chemicals, paints, cosmetics, explosives, fumigants, timber treatments, antifouling paints, cleaning products, raw materials, compressed gases, fuels, polymers, solvents, construction products, tattoo inks, and water treatment chemicals. New organisms, including:

	• substances used for the purpose of mitigating adverse impacts on the environment or mitigating emissions that contribute to climate change. Note that some of these groups are exempt from needing to register a trade name product.	• species that were not present in New Zealand before 29 July 1998 • those with containment approval (eg in a zoo or laboratory) • genetically modified organisms • species that have been eradicated from New Zealand.

In general, all products to be used for or on plants or animals requires approval under ACVM, while only products that are hazardous substances or a new organism also need approval under HSNO. Although the remit of the two regulatory systems differ, the majority of the products covered by the ACVM regulatory system are also captured by the HSNO regulatory system.



Additional definitions

Agricultural and horticultural products mean agricultural compounds including veterinary medicines. These are substances used to help manage plants and animals, and includes environmental inhibitors.

Joint Ministers means the Ministers for Regulation, Food Safety and the Environment.

Market failure means a situation where the free interaction of supply and demand doesn't result in resources being used most efficiently. Examples include where consumers do not have sufficient information to make informed decisions (information asymmetry) and where industry avoids the true cost of producing goods and services, such as pollution (externalities).

Regulatory systems are sets of formal and informal rules, norms and sanctions, given effect through the actions and practices of designated actors, that work together to shape people's behaviour or interactions in pursuit of a broad goal or outcome.

Regulated party / parties are a person or organisation that is subject to behavioural expectations, obligations, and/or sanctions within a regulatory system.

Functions within a regulatory system are the range of different activities that are collectively needed to form a regulatory system, and include:

- Policy Design
- Monitor and Evaluate
- Compliance and Enforcement

- Delivery
- Operational Policy
- Advice and Education
- Standard Setting
- Dispute Resolution.

EXP-24-MIN-0033

Cabinet Expenditure and Regulatory Review Committee

Minute of Decision

Approval Path for Agricultural and Horticultural Products Regulatory Review: Terms of Reference

Portfolios **Regulation / Environment / Food Safety**

On 23 July 2024, the Cabinet Expenditure and Regulatory Review Committee:

1 **agreed** to the terms of reference for the regulatory review (the review) into the approval path for agricultural and horticultural products, attached as Appendix 1 of the paper under EXP-24-SUB-0033;

2 **agreed** to the launch of the review;

3 **authorised** the Ministers for Regulation, Food Safety and the Environment to amend the scope of the review if necessary, provided this remains within the Agricultural Compounds and Veterinary Medicines and Hazardous Substances and New Organisms regulatory systems, and does not include the regulation of gene technology;

4 **invited** the Ministers to report back to Cabinet to seek decisions in Quarter 1 of 2025 following the completion of the review.

Sam Moffett
Committee Secretary

Present:
Rt Hon Winston Peters
Hon David Seymour (Chair)
Hon Nicola Willis
Hon Chris Bishop
Hon Brooke van Velden
Hon Simeon Brown
Hon Erica Stanford
Hon Louise Upston
Hon Mark Mitchell
Hon Andrew Bayly
Hon Mark Patterson
Hon Chris Penk
Hon Penny Simmonds

Officials present from:
Office of the Prime Minister
Officials Committee for EXP