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.

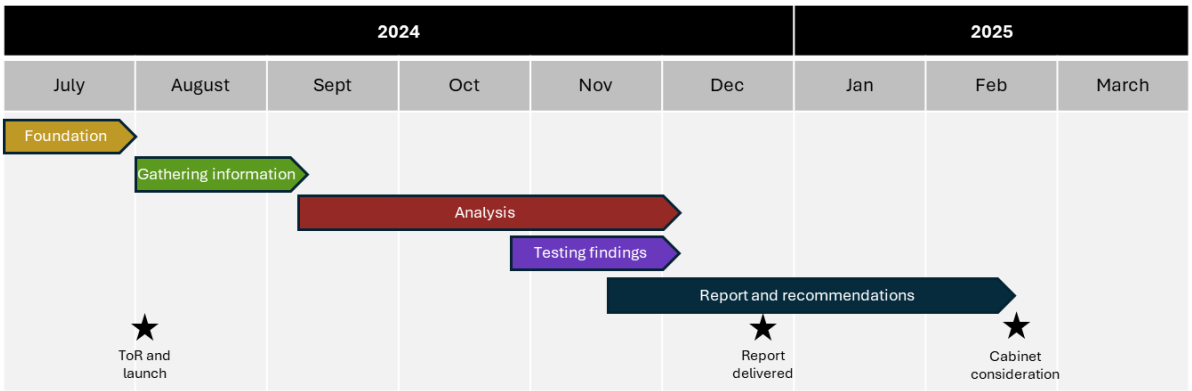
With related processes

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

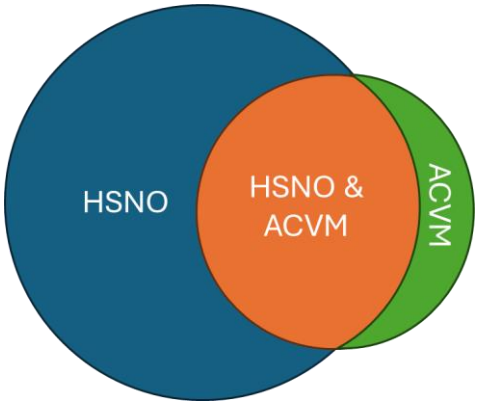
Regulatory systems relevant to assessment and approval of products

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.