



# **SUBMISSION**

on

# Agricultural and Horticultural Products Regulatory Review

to

Ministry of Regulation

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## **About the Fertiliser Association of New Zealand**

The Fertiliser Association of New Zealand is an industry association funded by member companies to address issues of common public good. Member companies include Ballance Agri-Nutrients Ltd and Ravensdown Ltd. Both are farmer co-operatives with some 35,000 farmer shareholders. Between them, our members supply the majority of fertiliser used in New Zealand. As co-operatives, they are driven by delivering best value to farmer shareholders rather than maximising the value of product sales.

The Association member companies have invested significantly in products, systems and procedures which support responsible nutrient management to enable a viable primary industry within environmental limits.

The Association submits on national policy and regulation, with the view that policy and regulation should be enabling, and that controls are both appropriate and necessary while providing for sustainable primary production.

The Fertiliser Industry is committed to supporting New Zealand's 2050 net zero emissions target and to enabling its farmer shareholders to achieve their ambitions in environmental management including reduction of agricultural greenhouse gas emissions.

#### Introduction

We welcome the opportunity to engage with the review of the approval pathway for agricultural and horticultural products under the Agricultural Compounds and Veterinary Medicines (ACVM) and Hazardous Substances and New Organisms (HSNO) regulatory systems. The review is timely.

#### Our submission is focused on:

- The balancing of risk, including the need for a common risk framework across the two pieces of legislation.
- Risk proportionate assessment.
- Opportunities to adopt and use the best of international trials and assessments.
- Sharpening focus to toxicology assessment rather than efficacy evaluation.

The regulatory systems for managing agricultural product risk are complex. Our submission largely focuses on questions directed at the opportunity for system improvement.

#### **Right Touch Regulation**

- Regulation of agricultural and horticultural products is about how we balance risk risk to the
  environment, risk to animal or plant health, human health, and trade while at same time
  ensuring that New Zealand farmers and growers have access to the best products to support a
  vibrant agriculturally based economy.
- A robust risk-based regulatory system is essential. However, the regulatory system is currently
  perceived as a barrier to innovation and investment in New Zealand, including investment by New
  Zealand companies within their own market. With two pieces of legislation, ACVM and HSNO,
  covering most products, cumulative delay is inevitable. Both the time frames and costs involved
  mean that it is hard to develop a viable business case for the development of new products, and
  it is difficult, expensive and slow to progress product through development and
  commercialisation.
- As New Zealand is a small market for international suppliers, such costs and uncertainty mean
  that there is a significant barrier to international companies who seek to register products in New
  Zealand. This means that there is a risk that New Zealand farmers and growers can only access
  dated products rather than newer, better, potentially lower-risk products being developed
  overseas.

#### Integration of risk management

- New Zealand is operating a dual regulatory system under HSNO and ACVM, each with different legislative approaches to risk assessment and management. There is a need for improved legislative commonality on the approaches to understanding, assessing and managing risk. Each legislative approach should be supported by a common risk assessment framework.
- Further consideration is needed as to how the two pieces of legislation interact with other

- legislation, such as the Animal Products Act 1999 and the Health and Safety at Work Act 2015.
- Regulation is part of the broader risk management system, with multiple agencies, partners, tools
  and accreditation systems. Users and applicators of product are core to a successful risk
  management approach. Risk management does not end with instructions and labelling on a
  product. How do legislative provisions align with the wider system such as industry initiatives,
  producer assurance schemes like Growsafe, or the work of the Veterinary Council etc?
- Do our current regulatory systems meet the needs and concerns of global companies and markets
  that buy New Zealand food products? Both industry engagement and the limited number of
  innovative products applying to be registered in New Zealand suggests it does not.
- Can we better align New Zealand regulatory practice with international regulatory practice and international mechanisms such as Codex?

#### Making the legislation work

- The current legislative frameworks are not sufficiently enabling, which puts significant pressure on the regulator in terms of testing boundaries:
  - For example, MPI Officials worked with industry to find a constructive approach to finding a regulatory pathway for inhibitors under the constraints imposed by the Act.
  - In the case of ACVM, it is the claims made for a product that dictate the requirement for registration, rather than the potential risk posed by the products.

#### **Regulatory practice**

- How can we better build on international assessments that are directly relevant to the New Zealand agricultural system what information can be used from jurisdictions with similar regulation frameworks, and where we know assessment is done to a high standard? Can regulatory assessments be based on assessments from overseas competent agencies with options to request additional information if needed to give confidence of application in New Zealand's farming systems and to manage the risks to trade? Can summaries of international data assessment packs be provided, where appropriate, rather than having to source raw data? What reliance can be placed on international trials?
- How can we triage risk assessment and focus on the products with greatest risk. Are assessments risk proportionate? Is there utility in applying the group standard approach adopted under HSNO, to assessment work under ACVM? Could research applications be treated under a common or group standard except where exceptional risks are identified? Should we assess products such as NBPT, that have been in use for decades, in the same way that we assess new products?
- New Zealand risk assessment processes are dependent on a small group of highly skilled experts in a global employment market where such expertise is highly sought after. Ensuring we retain and build this critical capability is key to ensuring an effective regulatory system. Is New Zealand regulatory expertise sufficiently supported with access to the latest science, risk assessment models and tools? Are we attracting skilled technical staff to move to, or stay in New Zealand?

- Are we enabling New Zealand's very scarce expert toxicology resource to focus on the major risks? Can the registration focus be narrowed to product safety and residue limits with less focus than currently occurs on efficacy claims, as other legislation e.g. Fair Trading Act and Commerce Act, protect consumers from unfair claims.
- Under ACVM there appears to be duplication between the role of data assessor and Officials'
  assessment. Does there need to be an accreditation programme for data assessors to improve
  accuracy and consistency of approach, with the intent that the regulator can assess the data
  assessment made with confidence, rather than duplicate the assessment? Is the dual approach
  to assessment unnecessarily stretching the limited skill-set too thinly?
- Can applicants be better positioned to provide better more streamlined applications through better communication on regulatory pathways and data requirements? Can applicants be better positioned to provide the information that supports the regulator to make good and timely decisions?

## **Communication and transparency**

- Clear legislative expectations on timeframes for assessment and communication of progress against timeframe is essential to build confidence for applicants. Such information is essential to better evaluate the performance of our risk management system. When legislative timeframes are not met then what mechanisms will be used to ensure agency compliance?
- Reporting on products registered should provide food processors and international food companies with confidence that risks are being addressed. Are there ways to better understand the concerns of food companies and potential risks in terms of overseas markets?
- It is not only for international markets that we seek to ensure that we have a well-managed regulatory system; the New Zealand public, as a food consumer, needs to have confidence in the system. What public reporting mechanisms are in place to ensure such confidence?

We welcome the opportunity to provide input and are happy to discuss any of the issues raised.

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