The regulation of environmental inhibitors in New Zealand

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Background

Agriculture contributes around 50% of New Zealand's total Greenhouse gas (GHG) emissions on a carbon dioxide equivalent basis. These emissions – mainly methane (80%) and nitrous oxide (15%) come largely from livestock predominantly grazing on pasture and through deposited dung and urine. New Zealand's contribution is less than 0.2% of the total global emissions, however as a major primary produce trading nation we take responsibility for reducing this over time in line with our international agreements and as a responsible global player.

Getting farmers the new mitigations technologies they need to reduce emissions is of strategic importance and is a government priority. It is crucial that there are more commercial mitigation technologies available to New Zealand farmers to enable them to reduce their emissions, or we in New Zealand risks not meeting our commitments under the Paris Agreement, falling behind our international competitors and losing key customers for our agricultural products.

While greenhouse gas inhibitors can reduce the environmental impacts of livestock, they can also pose risks to public health, agricultural security, animal welfare, and trade of primary produce and it is critical we ensure ongoing market access for New Zealand primary products. Also, as it is for any agricultural compound, if inefficacious, they increase the risk of not reducing emissions and posing an unreasonable cost on farmers. To manage these risks, current agricultural compounds containing inhibitors are regulated under the Hazardous Substances and New Organisms Act 1996 (HSNO) and Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM) and the Animal Products Act 1999.

Currently few overseas countries have either no or little regulatory oversight of inhibitors compared to New Zealand. Consequently, matters such as residue management and efficacy are left to the market to determine.

Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM)

The purpose of the ACVM is to prevent or manage risks associated with the use of agricultural compounds, including risks to:

- Public health
- Trade in primary produce
- Animal welfare
- Agricultural security
- Ensure that the use of agricultural compounds does not result in breaches of domestic food residue standards.
- Ensure that sufficient consumer information about agricultural compounds is available (Agricultural Compounds and Veterinary Medicines Act 1997, section 4).

Registering agricultural compounds under the ACVM requires a risk assessment involving the evaluation of information specifically related to the use of the substance. This assessment includes assessing the information to determine it is appropriate and scientifically robust, identifying the risks, determining risk mitigation options to manage the risks appropriately. Information includes trial data, information in the public domain, expert opinion, cross reference to existing registered products and regulatory decisions.

To import, manufacture, sell, or use an agricultural compound in New Zealand, it must either be authorised and registered under the ACVM or have been exempted from registration requirements. Registration is subject to the agricultural compound having either:

- A HSNO approval[1]; and/or
- Where the agricultural compound is a prescription human medicine under the Medicines Act an approval from the Director-General of Health (Agricultural Compounds and Veterinary Medicines Act 1997, Section 21 (5)).

In 2021, Cabinet agreed to strengthen the regulation of inhibitors used in agriculture by defining inhibitors as agricultural compounds under the ACVM[2] Feedback received during public consultation was strongly supportive of regulating inhibitors under the ACVM, as the lack of regulatory oversight results in reputational risks for exports, and uncertainty about the safety and efficacy of inhibitors may discourage people from using them.

The Agricultural Compounds and Veterinary Medicines (Inhibitor Substances) Order 2022 declared specified substances to be agricultural compounds for the purpose of the ACVM when it is intended for use as an inhibitor. Schedule 2 of the order listed forty-six inhibitor substances that were declared as agricultural compounds.

Accompanying regulations were amended to exempt inhibitors (on the Order) on the market at the time the Inhibitor Order came into force from ACVM registration requirements until 17 July 2024 (subsequently amended to 1 July 2026). Any inhibitor substance currently on the market will either need to register under the ACVM by that date or where such inhibitors are not registered by this date they must be withdrawn from the market.

Any inhibitor substance listed in the Inhibitor Order, but not already on the market when the Inhibitor Order commenced, would require registration before it can be marketed. Where the inhibitor substance is not on the Inhibitor Order at all, it continues to be not subject to the ACVM.

Regulatory Systems (Primary Industries) Amendment Bill

- This Bill will amend the definition of an agricultural compound in the ACVM to include substances used to mitigate adverse impacts on the environment or emissions that contribute to climate change (Agricultural Compounds and Veterinary Medicines Act 1997, Section 21 (4)).

It also sets a one-year transition period for inhibitor products to be registered under the ACVM (Regulatory Systems (Primary Industries) Amendment Bill, clause 2 (2)). This legislation is currently in its third reading in Parliament and is expected to become law in the next few months.

Progress and challenges with registration

Since 2022 one compound has been registered under ACVM as an environmental inhibitor and five other compounds are currently being assessed. This apparent slow uptake is for several reasons including low number of products suitable for the New Zealand market and companies currently do not require ACVM approval to make environmental inhibitor claims. Now that the bill is progressing, expectation is that the pace will pick up. Despite this modest registration uptake, the ACVM process so far has identified some aspects that could further enhance the registration process and are actively working to improve the system.

Support of registrants

Most applicants are new to the process and have been challenged by the detail and complexity of registration for inhibitors and the required emphasis on risks to trade, animal and public health.

MPI have dedicated additional resource to ACVM to assist with this and proactively encouraged registrants to engage with ACVM as soon as they can to understand the registration requirements. Since 2022, ACVM have convened an Inhibitor Operational Forum (IOF) involving companies that are considering registrations. This forum meets three times a year and acts as a clearing house and discussion opportunity for refinements to the registration process and associated issues. Membership of the IOF has grown to > 45 companies, underpinning

the growing interest in the space.

Efficacy confirmation

There are three levels of efficacy standard that are emerging to meet slightly different outcomes:
1. Product registration through ACVM.
2. Carbon accounting for Farm emission models and carbon markets.
3. National GHG inventory accounting.

All require sound evidential basis and statistical validation that a product works, but they differ in the level of detail required to fulfil their outcomes. Each level needs to ensure accuracy, consistency and focus on providing low compliance costs and maximum engagement.

In support of these objectives, ACVM registration applicants can make qualitative efficacy claims (reduces emissions) which have a lower burden of evidence than quantitative claims (percentage reduction of GHG). Applicants can still choose to make a quantitative claim, but these require significant cost to confirm at farm scale. The ACVM qualitative claim approach will support registrants to get on the market and develop that data to support the next level of efficacy.

Both carbon accounting and national inventory will require these more accurate and objective measures of GHG reductions at farm level and be in a form that can be used by carbon markets and collated to measure national impacts for UNFCCC purposes.

MPI is providing a key role in this space to lead and streamline systems that ensure that New Zealand has access to environmental inhibitors that enhance economic and environmental credentials, as world markets transition towards being more carbon conscious.