Regulatory stewardship in a changing world

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An agricultural compound and veterinary medicines (ACVM) policy perspective

- Understanding emerging and future risks
- Ensuring the regulatory settings are fit for purpose
- Regulations being an enabler
- People, businesses and regulators working together to reach an outcome

Why inhibitors are being regulated

- A number of drivers:
 - Animal and plant health
 - Food safety
 - > Trade
 - Stakeholder concern over lack of regulatory oversight
- DCD (dicyandiamide) residues in milk was a prime example

Why inhibitors are being regulated (cont.)

- Consultation on the regulation of inhibitors in 2020
 - Feedback from a number of industry sectors and inhibitor manufacturers indicated regulation of inhibitors was necessary
- Government agreed in 2021 that inhibitors required greater regulatory oversight and that the ACVM Act was the appropriate mechanism to manage potential risks arising from their use

Why inhibitors are being regulated (cont.)

- Animal and plant health
 - Inhibitors applied to animals or plants can have similar impacts on safety to that of regulated agricultural chemicals and veterinary medicines
- Food safety
 - Assessment of residues in food and food safety (dietary exposure) can be undertaken
- Trade
 - > Ability to manage trade risk from residues in the traded commodity



Why inhibitors are being regulated (cont.)

- ACVM Act risk management
 - Manage the risks posed by agricultural compounds to an acceptable level to support the overall goal of growing and protecting New Zealand
 - Gain the benefits from their use while keeping the risks of harm down to an acceptable level
 - Ensure controls are necessary and sufficient, and impose the least cost to the nation avoiding unnecessary regulatory intervention

Approach being taken

- Interim measure by an Order in Council declaring certain inhibitor substances as agricultural compounds
 - ➤ This approach has a limitation, if the inhibitor substance is not declared to be an agricultural compound then it may not be subject to the ACVM Act
- The permanent solution is to amend the ACVM Act so all inhibitors are subject to the Act



only in relation to inhibitors applied to plants or animals



Inhibitors Order in Council (the Order)

- There are 46 substances on the Order
- The Order defines an inhibitor as:

An inhibitor substance is an agricultural compound for the purposes of the Agricultural Compounds and Veterinary Medicines Act 1997 if, for the purposes of mitigating the adverse impacts of an agricultural activity on the environment, on sustainability, or on climate change, it is—

- (a) used or intended for use in the direct or indirect management of plants or animals; or
- (b) applied to a place on or in which there are plants or animals; or
- (c) applied to the feed or water of plants or animals.
- It came into force on 18 July 2022



2-year transition period

- In tandem with the Order, the ACVM Regulations were amended to allow 2 years for products already on the NZ market on 18 July 2022 to get registered
- If a product was not on the NZ market on 18 July 2022:
 - Registration is required before a product can be sold
 - Provisional reregistration is required for research and trials

Permanent solution to regulate inhibitors

- Amending the definition of 'agricultural compound' under the ACVM Act to cover inhibitors
- This will be done through a regulatory systems amendment bill
- When this bill is enacted then all inhibitors will be subject to the ACVM Act, including those not currently captured by the Order

The international regulatory landscape

- Regulatory oversight of inhibitors is variable (both for those used on plants or animals)
- This ranges from:
 - Nothing
 - Passive
 - Partial (some are regulated while others are not)
 - > Full

The international regulatory landscape (cont.)

- The reasons for this variability can include:
 - Does not fit well within existing regulatory regimes
 - Environmental mitigation technologies are still being developed
 - Lack of awareness
 - Their use is still limited
 - Policy is still evolving in countries on how to manage them i.e. either by amending existing a regulatory regime, or creating a new one



Haumaru Kai Aotearoa

Thank you

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