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DairyNZ feedback on the agricultural and horticultural products regulatory review

DairyNZ appreciates the opportunity to contribute to 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) Acts.

As the industry-good organisation representing New Zealand's 11,000 dairy farmers, DairyNZ is committed to helping farmers build profitable, sustainable, and resilient farm businesses through science, research, advocacy, and extension. Our purpose is to progress a positive future for New Zealand dairy farming.

This review comes at a crucial time. Farmers are at the forefront of addressing global challenges such as climate change and biosecurity. Innovations like methane and nitrous oxide inhibitors could offer powerful ways to reduce emissions while maintaining productivity. However, the current ACVM and HSNO regulatory system is overly complex, costly and slow. This is hindering innovation and delaying farmers' access to the best products to support stronger environmental, biosecurity, animal health and welfare, and production outcomes.

DairyNZ advocates for a streamlined approval pathway that enables faster access to critical innovations, supporting both the productivity and environmental sustainability of New Zealand's dairy sector.

Our work is affected by the current regulatory pathway in two main ways:

1. Restrictions to the ability to research and test potential greenhouse gas mitigation solutions for dairy farmers; and
2. Restrictions and delays in accessing biosecurity, animal health and welfare risk management tools for dairy farmers in the event of emerging or developing pests or diseases.

Our submission focuses on these challenges.

FEEDBACK

Restrictions impacting the research and testing of agricultural greenhouse gas mitigation solutions

1. Methane and nitrous oxide inhibitors represent a relatively new class of compounds designed to reduce livestock greenhouse gas emissions. Current legislation may not fully accommodate their novel characteristics.

2. We note that HSNO was primarily designed to manage chemical risks and genetically modified organisms, but it lacks clear provisions for evaluating new types of biological or chemical methane inhibitors.

3. The purpose of ACVM is solely about managing risks. Like others, DairyNZ believes that there is a balance to be struck between managing risks and ensuring that New Zealand farmers have access to the best products to support a vibrant agricultural sector.

4. Similarly, the process of proving the efficacy and safety of methane inhibitors under the ACVM Act can be lengthy and costly, particularly for products focused on environmental benefits rather than direct health outcomes. This has resulted in delays for testing and commercial rollout, with some companies abandoning efforts to bring their products to the New Zealand market.

5. DairyNZ is not advocating for a non-regulatory or self-regulatory approach to demonstrate the efficacy and safety of these technologies. We believe it is crucial to operate within existing legislation to maintain credible, independent regulatory oversight. This ensures that farmers and dairy companies can trust that the technologies they adopt are both safe and effective.

6. However, the regulatory process could be significantly streamlined, allowing for more constructive engagement between officials and industry stakeholders, while maintaining a science-based, independent evaluation. A more flexible approach is needed to encourage the availability and adoption of new technologies aimed at improving productivity and environmental outcomes.

7. As noted by DCANZ, it is essential to clearly define the acceptable level of risk and the specific requirements for applicants. For instance, a product already approved in an overseas jurisdiction with similar agricultural systems to New Zealand (including trial data) should be considered lower risk, allowing for quicker and easier acceptance.

8. International equivalence is essential for facilitating trade, ensuring legal consistency, promoting regulatory cooperation, fostering innovation, and addressing global challenges.

9. Exploring international equivalence opportunities with key market regulators such as Australia, the US, Canada and the EU may help further streamline approval processes by leveraging their systems. We recognise that there will always be a domestic lens to risk assessments.

10. International benchmarking can provide value, enabling identification of areas for alignment (i.e. FAO standards) to minimise duplication of effort for the regulator (and industry) while ensuring products meet best practice for our trading partners.

11. Improvements to the approvals pathway could significantly reduce timeframes and costs for applicants, making it easier to develop viable business cases for new products. Currently, the high costs, uncertainty, and slow progress in moving products from development to commercialisation create major obstacles. For international suppliers, New Zealand's small market, combined with these challenges, often deters participation. As a result, New Zealand farmers and growers can be left with access to outdated products, missing out on newer, more effective, and potentially lower-risk innovations developed overseas.

12. Other considerations for streamlining and improved regulatory implementation include:
    a. ACVM registration requirements and assessment processes that are proportionate to risk. As noted by the Fertiliser Association, there may be 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?
    b. Provision of a fee-for-service option to access pre-application assistance for companies to ensure they are on the right track early in product development.
    c. Improved legislative commonality on the approaches to understanding, assessing and managing risk between ACVM and HSNO.

Restrictions and delays relating to access to biosecurity, animal health and animal welfare risk management tools

13. Dairy farmers need timely access to new and emerging products and technologies to manage the risks from new and emerging pests and diseases. Farmers and veterinarians are missing out on alternatives to address important resistance and welfare issues. Access to products to support healthier animals and crops that make them more resilient to biosecurity threats are also critically important.

14. The current ACVM and HSNO approval pathways impose significant delays in getting those modern products into the New Zealand market. Fall Armyworm and the emerging High Pathogenicity Avian Influenza (HPAI) are real examples of pests and diseases that could or do impact the New Zealand agricultural sector, with an urgent need for innovative solutions.

15. As other submitters will have undoubtedly described, Spodovir is an example of a new and useful product for the control of Fall Armyworm which has been approved by the Australian APVMA using their Emergency Use permit system. Unfortunately, it will take some years for New Zealand farmers to have the same opportunity to benefit from its efficacy, as it has not been granted here and will need to proceed through a long evaluation and trial process to gain registration. The 2023 report by Sapere confirmed significant timeframes for achieving approval for any new and emerging product.[1]

16. Niche products and minor species products are vital to meet animal welfare and other requirements in small industries e.g. equine, deer and pork industry medicines, vaccines for New Zealand specific strains for Leptospirosis, Salmonella and other pathogens (many zoonotic with human health impacts).

17. Access to animal health innovation also has wider benefits than just for animals, including public health and emissions benefits. With a significant number of emerging infectious diseases in humans coming from animals (including COVID and more recently avian influenza), animal health, human health and environmental health are viewed as continuous, with the need for an integrated approach to all health risks. Lack of access to innovative new products that manage zoonotic disease threats in animals minimise the risks to human and environmental health.

[1] Page 30, Loan, J and Woock, K. 2023. The EPA's role and performance in assessing hazardous substances.

Additional issues

18. DairyNZ notes that the review is focused on the ACVM and HSNO regulatory systems. However, the Terms of Reference for the review notes that it *"…may include considering linkages or overlaps with other regulatory systems*."[2]

19. We wish to raise an issue with the Animal Products Act (APA) in relation to the management of research animals and byproducts resulting from research involving agricultural products such as methane inhibitors.

20. Currently, it is very difficult and expensive to conduct research evaluating methane inhibitors in dairy cows (e.g. feed additives), primarily because approval is needed from the milk processor after ACVM approval. This aspect of the application can be time consuming, expensive, prohibitive and unethical. If there are lengthy withholding periods for milk collection, animals must be culled or euthanised (in instances where meat cannot be collected). This has resulted in commercial companies withdrawing investment in New Zealand agriculture and, along with scientists, taking important research overseas.

21. We request that the regulatory review give due consideration to the full application process for testing inhibitors in New Zealand, not just the portion that relates to ACVM and HSNO approvals.

SUBMISSION ENDS

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[2] Page 3, Terms of Reference for the agricultural and horticultural products regulatory review.