Ministry for Primary Industries
Manatū Ahu Matua

Delegate's Decision

For granting an application for registration under section 21 of the Agricultural Compounds and Veterinary Medicines Act 1997

Product details

Trade name	RHDV1 K5	**Ref No**	V9646-01
Applicant	Canterbury Regional Council		
Application type	New registration		

Summary of considerations

The purpose of the application is to register Rabbit haemorrhagic disease virus (RDHV1a K5 variant), 08Q712 strain (lyophilised) for control of pest rabbits. It is a new strain of the currently registered product Rabbit Calcivirus Suspension (V9308).

A complete assessment of the product has been undertaken in accordance with the risk areas specified under the Agricultural Compounds and Veterinary Medicines Act 1997 and documented in the technical appraisal and risk assessment report. Risks posed by the product to public health, trade in primary produce, animal welfare and agricultural security have been adequately assessed.

Due to the nature of the proposed use of the product, matters relating to protection of non-target animals from infection have also been considered.

Chemistry and Manufacturing: Chemistry and manufacturing information conformed to the ACVM requirements and were sufficient to confirm the identity and quality of the product. Conformity to identity and product quality characteristics was identified as an important risk factor due to the potential for the introduction of unwanted contaminants, biologicals and/or RHDV strains (for example RHDV2). Evidence was provided to show that the trade name product will be manufactured as specified in the agreed product datasheet. The assessment confirms that there are sufficient controls in place to ensure that the identity and integrity of the product will be consistently achieved and maintained throughout its shelf life.

Stability trials conformed to MPI information requirements and it was concluded that the product will remain safe and efficacious when stored and used as specified.

Efficacy: Efficacy trials and data conformed to ACVM requirements and were sufficient to assess. The information provided shows that when used according to label instructions RHDV1 K5 will be effective at controlling pest rabbits. It was also shown that RHDV1 K5 can overcome immunity to a benign calicivirus strain which is present in many New Zealand rabbits, and which has been found to confer immunity to the current RHDV1 strain used for pest control. To ensure efficacy is achieved and that resistance to K5 is minimised, a condition has been proposed which requires use only as specified on the label.

Animal Welfare: Trials and data on humaneness to the target species conformed to ACVM requirements and were sufficient to assess. Expert advice has been considered in relation to the welfare implications of the virus on the target animals. When used in accordance with the proposed use pattern animal welfare outcomes will be similar to other comparable pest control options. RHDV1 K5 works in the same manner as the existing strain RHDV1 v351 which has been present in New Zealand since 1997. While there is minimal difference in welfare outcomes between RHDV1 K5, RHDV1 351 and alternative toxic agents, the welfare of non-target animals (pet rabbits) must also be considered as their exposure to RHDV can't be restricted to a contained application area as non-biological vertebrate toxic

agents can.

Evidence was provided to show that RHDV1 K5 is specific to the European Rabbit and no other species is impacted. All rabbits are susceptible to RHDV, including pet and farmed rabbits. RHDV1 strains have been present in New Zealand since 1997 and a registered vaccine is readily available.

Rabbit owners have been vaccinating against RHDV1 v351 for many years and this need will continue irrespective of K5 introduction. The efficacy of the current New Zealand registered vaccine to protect against RHDV1 K5 has been assessed as part of the application and found to be an acceptable means of managing this risk to non-target rabbits.

Residues: Information supplied was sufficient to assess risks associated with residues. No controls are proposed for the purposes of managing residues.

Trade: The product has been assessed in regard to the impact its use may have on trade in primary produce. No additional controls are proposed for trade purposes.

Public health: Due to the nature of the product and how it is intended to be used there were no additional public health matters that needed to be addressed over and above those covered under the Hazardous Substances and New Organisms Act 1996.

Submissions

The decision on registration has taken onto consideration a total of 167 public submissions. Of these, the majority were opposed based on animal welfare concerns (primarily vaccine efficacy and mode of action). Sufficient information has been provided to confirm that the vaccine will be efficacious, and will have the same duration of immunity against both RHDV1 K5 and RHDV1 v351. Animal welfare concerns that the target rabbits would suffer unnecessarily have also been considered.

Twenty two submissions supported the application, citing lack of effectiveness or cost of other control methods, and emphasizing the economic and emotional benefits of pest rabbit control, as well as environmental impacts of rabbits.

All submissions were considered as part of the application along with the benefits of registration. While there are significant concerns raised regarding animal welfare and inadvertent exposure to non-target rabbits, the benefits of registration are also relevant. The benefits identified primarily relate to improved pest control in the agricultural sector resulting in increased productivity. Other benefits considered included overcoming resistance to existing RHDV strains and negative effects of residues from pest control alternatives.

Existing Controls

RHDV is classified as an Unwanted Organism under the Biosecurity Act 1993. The applicant has been given permission by the MPI Chief Technical Officer under Sections 52 and 53 of that Act to release the RHDV1 K5 virus, propagate it or sell it (issued 19 February 2018). The permission decision document clearly outlines the benefits to the agricultural sector and the risks including those relating to hitchhiker organisms, illegal introduction, economic, cultural and human health. The conditions imposed require the virus to be transported, distributed, used and released in accordance with an operational protocol submitted as part of this application. The permission along with controls around release also requires verification of the strain prior to importation. It should be noted that these controls set under the Biosecurity Act are sufficient to mitigate risks identified under the ACVM Act and will not be repeated.

It is noted that under section s2A(4) of the Hazardous Substances and New Organisms (HSNO) Act 1996, the organism known as rabbit hemorrhagic disease virus, or rabbit calicivirus, is not a new organism.

The Canterbury Regional Council also proposes to allow use only by operators who sign their Operational Protocol. This will allow the registrant to maintain oversight and control of use of the product.

An approval for importation, clearance, and release of an Unwanted Organism under the Biosecurity Act 1993 (Biosecurity Act) has also been given.

Decision on Application

In consideration of the application all risks and benefits relevant to the ACVM Act have been identified and evaluated to inform the decision to grant or refuse the application. It has been determined that there is sufficient benefit for the registration of RHDV1 K5 and that the risks associated with its importation, manufacture, sale and use can be managed through the existing biosecurity permission conditions of registration set under the ACVM Act.

In addition to standard conditions applied to most agricultural compounds, it is proposed that the following conditions be applied:

1) A condition to require the product to be used only in accordance with label instructions (Condition 31).
2) A condition to restrict sale to the registrant of the product to ensure appropriate and sufficient information is transferred to the user (Condition 36).
3) A condition to report adverse events to facilitate the monitoring of non-target exposures (Condition 82).

On the basis of the above, the product as approved, and when imported, manufactured, sold or used in accordance with the conditions specified, is not likely to cause unacceptable risks to:

- public health
- trade in primary produce
- animal welfare or
- agricultural security.

On balance, there are sufficient benefits to warrant this product to be registered as a trade name product. When used in accordance with this approval, the product is not likely to cause residues in primary produce, food or food-related products that would breach domestic food residue standards. The assessed label content is deemed adequate to provide sufficient consumer information to allow the product to be used appropriately and safely and meets statutory labelling requirements.

Delegate's decision

Being satisfied of the matters above, and acting under delegated authority pursuant to the Agricultural Compounds and Veterinary Medicines Act 1997, this application for registration of a trade name product is approved, under section 21(1)(d) under the following conditions:

Conditions:

31. This product must only be used as specified in the label content.

36. This product must only be imported by the registrant or the New Zealand agent specified in the current approval.

60. The manufacture of the product must, at all times, conform to the product and manufacturing specifications approved as part of this registration.

61. The product must be labelled in accordance with the product and manufacturing specifications approved as part of this registration.

63. Persons responsible for the product at each stage throughout its distribution must maintain the product in a manner that ensures it conforms to the approved product and manufacturing specifications through to the product's retail sale.

65. The registrant must, as soon as practicable after becoming aware of new information, advise MPI of any new information that relates to the relevance, reliability or correctness of information provided at the time of registration and upon which the decision to register the product was made.

66. No advertisement for the product may:

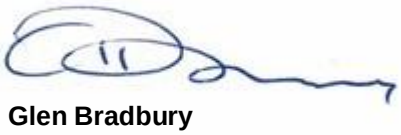
(a) include content or be presented in a manner that does not conform to the approved product and manufacturing specifications (this includes approved uses);

(b) contain false or misleading claims, statements or information in relation to the product; or

(c) without limitation to the generality of (b), directly or by implication make false or misleading claims or statements about the regulatory status of the product under the ACVM Act.

82. For the purposes of this condition, an adverse event is any event that brings into question the relevance or reliability of information provided at the time of registration and upon which the decision to register the product was made.

The registrant must notify MPI of an adverse event in relation to the product, immediately upon becoming aware of the event, where the event has or may have significant implications for the continued use of the product.

Signed Under Delegated Authority By:	 **Glen Bradbury** Manager ACVM Appraisals and Programmes Regulation and Assurance
Date	21 February 2018