Ministry for Primary Industries
Manatū Ahu Matua

OIA17-0170

20 APR 2017

Kip Bodle
CEO
Deosan Manufacturing Limited
c/-of FYI website

Dear Kip Bodle

OFFICIAL INFORMATION ACT REQUEST

I refer to your official information request on 24 March 2017 for "all information pertaining to the application from Ecolab" for the teatspray Hibitane2 Plus and information "on the assessment of the application and in granting the extension."

In your request, you state that the extension was "progressed under urgency." For note, the urgency that was requested by Ecolab related to a requested review of decision under section 77a of the Agriculture Compounds and Veterinary Medicines (ACVM) Act. This review of the decision was unrelated to the extension of the product shelf life or its approval.

The following information is released to you under the Official Information Act 1982 (OIA):

Hibitane2 Plus is a post-milking teat sanitiser product approved as an aid in the control of mastitis in dairy cattle. Ecolab applied to extend the approved shelf life of the product in November of 2016. The delegate approved the application on 3 March 2017.

The Ministry for Primary Industries (MPI) contacted the registrant when the assessment was completed to advise of the outcomes and to provide advice resulting from the assessment. This advice included instruction on changes to the product registration unrelated to the requested variation:

- a requirement to amend a label statement relating to the product's content, and
- a requirement to provide additional data.

On receiving this advice, the registrant requested a review of decision specific to these two issues. Because the assessment of the application went significantly beyond the regulatory time frame of 40 working days from acceptance in November 2016, EcoLab requested that the review of decision be conducted with urgency to finalise the approval of the variation.

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This review found that the decision to approve the 12 month shelf life should be upheld, but that the decisions regarding the label statement and additional data should be altered. Although the label amendments were instructed to provide more clarity to the consumer, it was determined that an immediate change was not required and could be actioned at a later variation. Additionally, on further review of all data and information available, the requirement to provide additional data was determined unnecessary relative to the risk profile of the product.

All of the documentation associated with the application and assessment of Hibitane2 Plus has been withheld under the following sections of the OIA;

- 9(2)(b) – to protect information where the making available of the information—
  - (i) would disclose a trade secret; or
  - (ii) would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information; and
- 9(2)(ba)(i) – to protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied.

MPI is satisfied that in the circumstances of this case, the withholding of the information is not outweighed by other considerations which render it desirable in the public interest to make the information available. You have the right under section 28(3) of the OIA to seek an investigation and review by the Ombudsman of our decision to withhold information.

Yours sincerely

Allan Kinsella
Director Systems Audit, Assurance and Monitoring