

19. Delegate's Decision

SATISFACTION AGAINST s5A, 5B AND 5C OF THE AGVET CODE

I am satisfied that the proposed product meeting the requirements of Agvet Code Regulations Schedule 6.1(1)(a), (b), (c), (d), (e), (f) and (g) and is considered to be closely similar to the reference product.

Satisfaction of sections 5A, 5B and 5C of the Agvet Code requirements is drawn from the fact that the proposed product was found to be closely similar to the nominated reference product and that the reference product is registered.

Therefore the APVMA has previously assessed equivalent risks in terms of s5A (safety), s5B (efficacy) and s5C (trade) and found the risks to be acceptable if the label directions are followed

FOR OFFICIAL USE ONLY

THIS DOCUMENT MAY CONTAIN CONFIDENTIAL COMMERCIAL INFORMATION