final report

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APVMA assessment dag removal enzymes

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Executive summary

Meat and Livestock Australia (MLA) is working with two commercial partners to progress development of an enzyme-based solution to the feedlot dag problem. To assess the level of data collection required during trial work, it is first necessary to obtain clarity around the Australian Pesticides and Veterinary Medicines Authority (APVMA) requirements for future use of the products, especially to identify if the dag removing product is captured by the APVMA legislation and thus requires registration as a veterinary chemical product.

This project was commissioned to assess this aspect, and if registration is required, to provide guidance on the documentation required to support a registration application.

Redcap Solutions reviewed the relevant sections of the Agricultural and Veterinary Chemicals Code Regulations and initiated consultation with the APVMA in February 2019. This consultation included submission of a formal Pre-Application Assistance application to the APVMA, on the advice of the agency, in order to obtain definitive written advice confirming the regulatory status of the proposed formulation. Written advice was received in May 2020 which confirmed that the proposed product does not require registration by the APVMA.

Further consideration of the testing requirements and documentation necessary to achieve registration was therefore not required.

There is now a clear regulatory pathway for the future research and development of enzyme-based topical solutions for removal of dags from cattle hides.

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1 Background

Meat and Livestock Australia (MLA) is working with two commercial partners to progress development of an enzyme-based solution to the feedlot dag problem. To assess the level of data collection required during trial work, it is first necessary to obtain clarity around the Australian Pesticides and Veterinary Medicines Authority (APVMA) requirements for future use of the products, especially to identify if the dag removing product is captured by the APVMA legislation and thus requires registration as a veterinary chemical product.

This project will assess this aspect, and if registration is required, will provide guidance on the documentation required to support a registration application.

2 Project objectives

To determine the APVMA registration requirements for a topically applied enzyme-based dag solution and provide recommendations on the testing/documentation to support the registration application.

3 Methodology

Redcap Solutions was requested to carry out the following tasks:

1. Undertake an initial assessment of the APVMA legislation to determine whether the enzyme solutions proposed for development by MLA's commercial partners would likely be:
    a. a substance classified as a "veterinary chemical product" as declared under Schedule 3AA Part 2 of the Agricultural and Veterinary Chemicals Code Regulations 1995 (Compilation No. 39) or;
    b. a substance declared not to be a "veterinary chemical product" under Schedule 3AA Part 3 of the Agricultural and Veterinary Chemicals Code Regulations 1995 (Compilation No. 39).

2. Undertake additional discussions with APVMA to obtain further direction on likely assessment, with a view to avoiding the onerous registration process.

3. Based on these discussions, provide guidance on the range of testing and documentation required to support the use of the product/registration if required.

In order to complete Task 1 the relevant sections of the Agricultural and Veterinary Chemicals Code Regulations were reviewed and consultation with the APVMA was initiated on 14 February 2019. This consultation requested clarification of the regulatory status of the proposed enzyme solutions, and whether they were captured by the Schedule 3AA Part 2, specifically the entry for Item 3 in the Schedule being "*Enzymes supplied or used for administration to an animal by any means, or for consumption by an animal, except excluded nutritional or digestive products".*

The consultation continued with the APVMA and subsequently also with the Department of Agriculture, Water and the Environment until April 2020 when a formal Pre-Application Assistance application (Tier 1) was submitted to the APVMA on the advice of the agency in order to obtain definitive written advice confirming the regulatory status of the proposed formulation.

Based on the outcome of this PAA application (PAA ID 124867) Tasks 2 and 3 above were not required to be undertaken.

4 Results

Pre-Application Written Assistance was received by Redcap Solutions in response to PAA ID 124867 on 18 May 2020. In this advice the APVMA confirmed that the proposed product does not require registration as a veterinary chemical product as, in the APVMA's view, whilst Part 2 of Schedule 3AA to the Agvet Regulations declares at Item 3 "*Enzymes supplied or used for administration to an animal by any means, or for consumption by an animal, except excluded nutritional or digestive products"* to be veterinary chemical products for the purposes of the Agvet Code, the proposed product falls outside of this definition, as the proposed product is for ***application to*** rather than ***administration to*** an animal.

The APVMA assessment further advised that Part 3, Division 3.1 of Schedule 3AA to the Agvet Regulations sets out those substances or mixtures declared NOT to be veterinary chemical products for the purposes of the Agvet Code. These include, at Item 6:

"*Any product applied topically to the teeth, hair, fur or intact skin of an animal to cosmetically alter the animal's appearance or odour, that:*

(a) contains no antiseptic, antimicrobial, or antibiotic active constituent; and
(b) is solely for cosmetic purposes; and
(c) is not claimed to have benefits other than cosmetic benefits; and
(d) is not supplied or used for therapeutic benefit other than to cosmetically alter the animal's appearance or odour.

The authority concluded that "*The proposed product, which is to be applied topically and for the purpose of altering the animal's appearance and/or odour, may thus be so described; and is therefore declared by the Agvet Regulations not to be a veterinary chemical product."*

On this basis the proposed enzyme solution does not require registration with the APVMA.

5 Discussion

Written advice has been received from the APVMA that the proposed enzyme-based solution for removal of dags from cattle hides does not require registration with the regulator as a veterinary chemical product. Further consideration of the testing requirements and documentation necessary to achieve registration is therefore not required.

The objective of the project has been met.

6 Conclusions/recommendations

Further research and development of the proposed enzyme-based formulations can now be undertaken without any requirement for regulatory approval of field trials, or subsequent registration of the finished products by the APVMA.

7 Key messages

There is now a clear regulatory pathway for the research and development of enzyme-based topical solutions for removal of dags from cattle hides.