Australian Government
Australian Pesticides and Veterinary Medicines Authority

Registration Self-assessment Tool (Veterinary)

15 November 2017

This self-assessment tool is based on relevant provisions of the Agvet Code and associated legislative instruments. Whether your product is required to be registered can only be authoritatively determined by applying the legislation. The questionnaire contains terms that are defined in the Agvet Code and a number of technical terms.

Every effort has been made to ensure the result of the self-assessment tool is accurate. However, the APVMA cannot and does not guarantee the accuracy of the answer, which will be determined by your own responses to the questions. The result you are provided should be treated as guidance and assistance, and should not be relied upon as a substitute for obtaining expert advice or an APVMA Item 25 assessment.

1. Product Name: **Feed Ingredients & Additives**

2. The product is:
   - ❌ (a) An allergenic substance
   - ❌ (b) A sheep brand
   - ❌ (c) A teat sealant
   - ✔ **(d) None of above**

3. Does the product have a chemical or biological component/effect: **Yes**

4. The product is:
   - ❌ (a) Applied to an animal -
   - ❌ (b) Administered to an animal -
   - ✔ **(c) Fed to, and voluntarily consumed by an animal**
   - ❌ (d) Applied to animal genetic material (sperm, ova or semen).

5. Does the product contain any ingredients that are:
   (a) a hormone
   (b) material from a vertebrate (if the product is to be consumed by ruminants)
   (c) an antibiotic listed in schedule 2, 3, 4, 7, 8 or 9 of the Poisons Standard
   (d) an antibiotic listed in schedule 6 of the Poisons Standard, other than a preservative in the product, or
   (e) an ingredient listed in the relevant APVMA legislative instrument?
   No

6. Is each ingredient of the product

A. a substance of plant or animal origin that is edible by an animal, including:
(a) an edible grain and a processing by-product of an edible grain; and
(b) whey powder and any other milk by-product

Or
B. listed in at least one of the following, for the purpose and in accordance with any other restrictions specified on the list:
(a) Para 3(a)-(c) of Standard 1.3.3 of Food Standards Code
(b) Clause 11, or Schedule 3 or 4 of Standard 1.3.1 of Food Standards Code
(c) A determination under section 8B of New Zealand's Agricultural Compounds and Veterinary Medicines Act ("the GRAS Register for Oral Nutritional Compounds") as published at 1 January 2015
(d) Annex I of the European Union Register of Feed Additives (other than a category 5 substance), and a expiry date is listed for that ingredient
(e) Parts 573, 582 and 584 of Title 21 of the Code of Federal Regulations of the United States of America, as existing at the time of supply
(f) Chapter 6 of the Official Publication of the Association of American Feed Control Officials
(g) Handbook of Pharmaceutical Excipients (for products for canine and equine only)
(h) An ingredient determination of the APVMA

Yes

7. Is the product manufactured under one of the following QA systems, noting the QA system must be appropriate for the product:
(a) APVMA GMP
(b) an Australian animal feed industry code of practice (such as FeedSafe or the FIAAA CoP)
(c) an Australian Standard for animal feed manufacture (in particular, AS 5812-2011)
(d) an animal feed quality standard of the United States of America or the European Union (such as FAMI-QS)?

Yes

8. Does the label contain?
(a) Name of product
(b) Signal words required by Poisons Standard
(c) Instructions for safe handling (may be in accompanying material)
(d) Application / dosage rate
(e) Analysis of key ingredients to support claims (may be in accompanying material)
(f) List of ingredients (may be in accompanying material)
(g) Batch number and expiry date (may be in accompanying material)
(h) Name, address and phone number for person responsible for marketing the product

(i) That the product is supplied by a veterinary surgeon if the product can make claims about treating a disease or injury on that basis

(j) Information required by EU Commission directive 2008/38/EC about treating or alleviating a disease or condition or modifying the physiology of an animal

Yes

9. Does the product claim to cure? **No**

11. Does the product claim to alleviate or prevent a disease or condition? **Yes**

12. Is the product supplied by or in accordance with the instructions of a vet? **No**

13. Are the claims of the product supported by:

(a) Scientific studies that are published in a reputable journal, refereed scientific journal, or that are of a standard publishable in such a journal, or

(b) Compliance with EU Commission Directive 2008/38/EC?

Yes

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No Registration Required

Thank you for using the APVMA's Registration Self-assessment Tool (Veterinary). Every effort has been made to ensure the result of your self-assessment is accurate. However, the APVMA cannot and does not guarantee its accuracy, because the result has been determined from the responses you gave to each of the questions. The result of your self-assessment should be treated as providing guidance and assistance, and should not be relied upon as a substitute for expert advice, including options such as an Item 25 assessment by the APVMA.

Based on your responses it is believed that **Feed Ingredients & Additives** probably does not require registration under the Agricultural and Veterinary Chemicals Code Act 1994. Please keep a copy of this PDF file, which details your responses, for your records.

You might decide to supply your product to the market on the basis of this self-assessment. If so, you need to fully consider the disclaimer above. While your self-assessment and its outcome could be taken into account, if it is determined in the future that your product does require registration you risk being found to have committed an offence against the Agvet Code. Should you seek to rely on the tool to establish a defence to any future offence you may be required to satisfy a court that you approached the self-assessment honestly and reasonably.

If you wish to be certain about whether your product requires registration, you may apply for a formal assessment by the APVMA. There are fees associated with applying. Full details are available through www.apvma.gov.au.

Your obligations under other regulatory schemes or systems have not been determined through this process.

For further information:

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