Australian Government
Department of Agriculture and Water Resources

Submission on the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017

Section A: General information

Purpose of this form	For individuals and organisations to provide submissions on the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017. Use this form to provide a submission or to write a long-form response. You can also attach a separate response.
Before applying	See Agriculture and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017.
Closing date	19 July 2017
To complete this form	Save the document to your computer.
Your submission must include	☒ a completed and signed submission form ☐ where relevant, supporting information from organisations, written on their official letterhead.
Post or email (preferred) your submission	Agvet Chemicals Sustainable Agriculture, Fisheries& Forestry Division Department of Agriculture and Water Resources GPO Box 858 Canberra ACT 2601 Email agvetreform@agriculture.gov.au

Section B: Applicant

1 Organisation name (if applicable) Australian Veterinary Association

2 Contact address

Postal address PO Box 4257_____

Suburb/town/city Kingston_____ State/territory ACT_____ Postcode 2604_____

3 Contact person

Given name(s) Dr Melanie Family name Latter

Work phone 02 6273 0064 Mobile phone 0422 642 648

Email melanie.latter@ava.com.au

Section C: Confidentiality

4 Is all of your submission confidential?

No ☒

Yes ☐ Clearly mark the submission 'In confidence'

5 Is part of your submission confidential?

No ☒

Yes ☐ Clearly mark the relevant section(s) 'In confidence'

Section D: Publication of submissions on the department website

Unless you request otherwise, the department will publish your name, organisation and the title of your submission on its website. Your contact information will not be made available.

6 Do you agree to your submission being made publicly available?

No ☒ Go to question 8

Yes ☐ Go to question 7

7 Do you agree to your name and state/territory being listed?

No ☒

Yes ☐

8 Do you agree to the department contacting you about your submission if required?

No ☐

Yes ☒

Section E: Submission type

9 What type of submission are you making? (select one box only)

☒ Response to key topics in the draft report → Go to section F

☐ Long-form response to the whole draft report → Go to section G

☐ Separate response in an attached document → Go to section H

Section F: Response to key topics in the consultation paper

Support your answers with references.

10 Comment on clarifying confidential commercial information provisions.

N/A

11 Comment on simplifying reporting requirements for annual returns.

The AVA supports the proposal to align information requirements and timing with the existing levy reporting. We understand that this will reduce the regulatory burden on industry. We also understand that it will still be mandatory for reporting of total product quantities supplied annually, and we support this.

We do however, have some concerns about reports that compliance in annual reporting is currently poor. We suggest that this review is an opportunity to address the issue of enforcement of mandatory reporting to ensure it occurs consistently. This would assist efforts in surveillance of antimicrobial use in Australia, and thus help authorities to address the growing problem of antimicrobial resistance. Without the data it is difficult to monitor and assess the volume of usage of antimicrobial products. We believe that perhaps stronger penalties need to be in place to reduce or eliminate non-compliance.

12 Comment on increasing the APVMA's flexibility to manage minor errors in applications at preliminary assessment.

N/A

13 Comment on APVMA amendment of the relevant particulars or conditions in a variation application.

N/A

14 Comment on timeframe for notifying FSANZ about variations to the MRL Standard.

N/A

15 Comment on enabling a person to vary the particulars of a label approval that is suspended.

N/A

16 Comment on the amendments to the definition of 'expiry date'.

N/A

17 Comment on adding the potential for human exposure to antimicrobial resistant microorganisms as a specific safety consideration.

We understand the intent of this new provision, is to ensure that the APVMA includes assessment of the potential for a product to give rise to antibiotic resistant organisms as a result of its use. In principle we support this, provided that this consideration is done in a manner that takes relative risk into account. For example, use of *any* antibiotic inappropriately can theoretically lead to antimicrobial resistance. Taken to its extreme, this provision could make it difficult for the APVMA to approve registration of any new antimicrobial product. So there needs to be clarification about how this new proposed provision is intended to be implemented. There are many resources that could assist the APVMA in assessing the relative risk of certain classes and generations of antibiotics, in order that the risk assessment can be evidence-based (some examples of these resources are provided in section 21 below). The potential for any product to give rise to antibiotic resistant organisms depends very much on how it is used – so appropriate labelling instructions about use can overcome many of these potential risks.

Finally, we think that the proposed provision should be worded as: "the potential for human OR ANIMAL exposure to antimicrobial resistant microorganisms resulting from the use of the constituent" as it is not only humans, but also animals at risk of the serious consequences of antibiotic-resistant infections.

18 Comment on including civil penalty provisions for false or misleading information.

N/A

19 Comment on other minor and technical amendments to the Agvet Code and the Administration Act.

20 Other comments. This could include additional information or relevant issues to be raised.

A large part of this initial consultation appears to be most relevant to product registrants rather than the AVA. Hence we have answered as N/A above, where this applies. We do look forward to assisting the Department with the subsequent stages of consultation on AgVet chemical reform, specifically the stages associated with harmonisation of veterinary prescribing legislation, and off-label use.

→ Go to section H

Section G: Long-form response to the consultation paper

21 Support your response with references. Attach additional sheets if necessary.

Resources as mentioned in section 17, above:

- Fact sheet on Veterinary use of antibiotics highly important to human health
- Fact sheet on prescribing veterinary antibiotics
- Fact sheet about safe handling of animals being treated with antibiotics - you might like to use this as information for people administering antibiotics in stock feed

Section H: Applicant declaration

To be completed by the person listed in section B of this application.

I understand that:

- the Australian Government reserves the right to refuse to publish submissions, or parts of submissions, that contain offensive language, potentially defamatory material or copyright infringing material
- a request may be made under the *Freedom of Information Act 1982* for a submission marked confidential to be made available. Such requests will be determined in accordance with provisions under that Act
- if I provide personal information about an individual other than myself, I must make that person aware of the privacy notice in section I of this form and draw their attention to the department's privacy policy.

Signature (type or sign your name) Dr Melanie Latter_____

Date (dd/mm/yyyy) 18 July 2017_____

Full name Melanie Latter _____

Section I: Privacy notice

'Personal information' means information or an opinion about an identified individual, or an individual who is reasonably identifiable.

The collection of personal information by the Department of Agriculture and Water Resources in relation to this submission is for the purposes of gathering information on the Exposure Draft of the Agricultural and Veterinary Chemicals (Operational Efficiency) Bill and related purposes. If you do not provide this information, the department will be unable to contact you to discuss your submission.

Under the *Freedom of Information Act 1982*, submissions marked confidential may be made available. Such requests will be determined in accordance with provisions under that Act.

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