Submission on Streamlining Regulation of Agricultural and Veterinary Chemicals

Section A: General information

**Purpose of this form**
For individuals and organisations to provide submissions on streamlining regulation of agricultural and veterinary chemicals.

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 (Streamlining Regulation) Bill 2018](http://www.agriculture.gov.au).

**Closing date**
22 August 2018

**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) - Dairy Australia Limited**
2. **Contact address**
   - Postal address - Level 3, 40 City Road
   - Suburb/town/city – Southbank
   - State/territory – Victoria
   - Postcode - 3006
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 provisional registration of chemical products

Support in principle.

Early access to new effective pesticides in pasture/fodder production could prove attractive in resolving current or future pest management issues for dairy farmers. Similar advantages may apply to registrants of new veterinary treatments where efficacy trials involving animals can be expensive. Early sales to assist costs of such trials could be advantageous to encourage expanded options for farmers.

Dairy Australia can see advantages in having earlier access to chemicals for particular uses, acknowledging that the risks need to be carefully managed:

- The benefits of this approach are that registrants may bring products onto the market (or extend the approved use) in situations where the costs of generating efficacy data are too high to justify registering the product (or seeking a variation to the product) under current arrangements.
- The risks of this approach are that the provisionally registered products are not effective, wasting time, money and potentially leading to animal welfare (vet chems) and productivity losses for users. In the most extreme case, registrants could market and sell a product with no efficacy for 3-5 years before it would be removed from the market, potentially ‘gaming’ the AgVet chemical registration system. Users may also ‘experiment’ with different doses and uses if they think the product is not working, which could pose other safety risks and challenges to State ‘Control of Use’ regulators.

Under a provisional registration system, the APVMA must be satisfied that the product has the potential to be efficacious in its intended use, even if the data provided does not provide conclusive evidence. For example, the active should be capable of having an effect and the product may have international data, evidence of having been registered overseas for this use or bench top efficacy studies.

Consequently, under provisional registration provision, registrants of ‘bona fide’ products would be able to convince the APVMA that the basis for efficacy is there, and then be given time (and the ability to generate sales to pay for costs) to generate additional Australian trial data. Registrants are generally aware of whether the efficacy data they possess is likely to be sufficient to support the registration of a product, so registrants should be able to indicate whether they are seeking to have their product assessed under the provisional registration provisions.

The APVMA may also need to develop a process for efficient assessment of requests from applicants wishing to vary the formula or instructions for use subsequent to being granted provisional registration, as the efficacy trial work may directly impact on the provisionally approved registration and/or label particulars.

The timeframes for provisional registration should be sufficient to undertake the necessary efficacy work (1-2 calendar years), completing the reports and the APVMA’s assessment of this work. A three-year timeframe should be sufficient. The APVMA requirement for an agreed trial design and schedule in place prior to granting provisional registration would be appropriate. This gives the best chance of registrants meeting their data generation obligations.

However:

- Notwithstanding the above, Dairy Australia does not see how the proposal easily allows expanded access to generic active ingredients for minor and major crops where registrant commitment to developing data is not supported by a market advantage. This is important to the dairy industry in relation to minor and emerging fodder crops e.g. chicory or pasture brassicas.
• Provisionally registered products should not be able to be used as reference products to support other applications.
• Dairy Australia expects the “discretion” criteria used by APVMA would be applied in a transparent way, while supporting the approach in principle for minimising the provisional registration of “snake oils”, which are unlikely to ultimately benefit the end user and may impose risks.

11 Comment on accreditation of assessors

Do not support.

While Dairy Australia accepts the necessity of using external assessment services, we do not support the development of a legislative instrument to prescribe an accreditation scheme for assessors.

The statutory timeframe established for the assessment of efficacy/performance data for a pesticide is usually shorter than that required for the assessment of other modules such as residues. Dairy Australia is uncertain how the proposal would provide a substantive benefit unless a future shortage of efficacy reviewers is anticipated. If a shortage is anticipated additional information is needed on the costs associated with the APVMA managing accreditation and any vetting or peer review process related to that accreditation.

Managing the quality of service and conflict of interest may best be managed through commercial service contracts and/or under conditions of employment. Reviewers would need to be contracted independently of chemical companies.

12 Comment on approval and registration for prescribed active constituents, products and labels

Support in principle.

Dairy Australia supports changes to registration processes that reduce the costs and timeframes required to register and vary the registration of low risk products. We note that the changes being contemplated would apply only “for those active constituents, chemical products and labels where minimal or no technical assessment was required”.

This streamlined registration process is supported for image registrations and potentially for products that meet an agreed standard (aka Listed Chemical Products), but requires further detail relating to the types of applications and circumstances in which it is proposed to be applied.

13 Comment on data protection incentives (limits on use of information)

Support in principle.

Dairy Australia suggests a structured combination of extensions to data protection periods coupled with fee waivers and application discounts would likely be a significant incentive to all potential pesticide registrants to pursue an approach to a wider suite of uses and crops on labels—particularly generic pesticides—keeping costs of registration reasonable and therefore pest control costs to dairy farmers relevant and cost-effective.

Quicker market access (provisional registration as per item 10) and reducing the costs and timeframes of registration (by varying APVMA processes) are alternatives likely to have less financial impact on farmers. Improved data protection period extensions may be appropriate where residue or environmental or trade issues need more data support.

The current data protection opportunities available to registrants as incentives to add new uses and minor crops is limited. Dairy Australia welcomes the in-principle concept of giving registrants the opportunity to recoup expenses potentially associated with smaller market (crop) opportunities (particularly smaller major crops and minor crops) when applying for label uses. An effective
“reward” system for new active pesticide label use registrations that expands initial labels to include smaller and minor crops would likely benefit dairy farmers.

However:

- It is not immediately obvious how such a system would encourage generic chemical registrations to expand label uses to minor crops or smaller major crops such as brassica pastures and emerging crops like chicory and plantain. Dairy Australia would encourage the use of fee waivers for label extensions such as used in Canada as a means by which labels for existing generic compounds could be expanded. ([http://laws-lois.justice.gc.ca/eng/acts/P-9.01/](http://laws-lois.justice.gc.ca/eng/acts/P-9.01/))

- A difficulty for dairy farmers is that agricultural pesticide use is primarily based around pastures and fodder production. Currently, fodder crops and pasture are regarded in a broad “non-minor crop category” providing restricted opportunity for registrants to pursue pest management solutions in small or emerging crops or particular segments of importance to farmers. As a result, the proposal as it currently stands, would provide few opportunities for the dairy industry stakeholders to benefit from possible extensions to data protection. Dairy Australia suggests the scope could be broadened to allow the future inclusion of the outcomes of work currently underway by the Codex Committee on Pesticide Residues (CCPR), in which the classification of Class C Primary feed commodities of plant origin, is being revised. As a first step CCPR has agreed on the creation of a number of subgroups (see below – Appendix X) and it is anticipated that as this work progresses representative crops will be identified within these subgroups. Dairy Australia believes such commodity groupings would assist in the development of relevant new pesticide products for the dairy industry via the addition of important label use patterns for minor pasture and fodder crops, whereby registrants adding label uses and minor crops attracted data protection extensions.

<table>
<thead>
<tr>
<th>REP18/PR APPENDIX X</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROPOSED STRUCTURE OF CLASS C: ANIMAL FEED COMMODITIES</td>
</tr>
<tr>
<td>(For further development by the EWG on the revision of the Classification of Food and Feed)</td>
</tr>
<tr>
<td>CLASS C: ANIMAL FEED COMMODITIES</td>
</tr>
<tr>
<td>Type 11 Feed commodities of plant origin</td>
</tr>
<tr>
<td>Group 50 Legume feed products</td>
</tr>
<tr>
<td>- Subgroup 050A: products with high water content (forage)</td>
</tr>
<tr>
<td>- Subgroup 050B: products with low water content (hay)</td>
</tr>
<tr>
<td>- Subgroup 050C: processed products (like silage, meal, hulls)</td>
</tr>
<tr>
<td>Group 51 Cereal grains and grasses (including pseudocereals) feed products</td>
</tr>
<tr>
<td>- Subgroup 051A: products with high water content (forage)</td>
</tr>
<tr>
<td>- Subgroup 051B: products with low water content (hay, straw)</td>
</tr>
<tr>
<td>- Subgroup 051C: processed products (like silage, bran, hulls)</td>
</tr>
<tr>
<td>Group 52 Miscellaneous feed products</td>
</tr>
<tr>
<td>- Subgroup 052A: products with high water content (forage, beets, tops)</td>
</tr>
<tr>
<td>- Subgroup 052B: products with low water content (hay)</td>
</tr>
<tr>
<td>- Subgroup 052C: processed products like processing residues (meal, hulls, dried pulps),</td>
</tr>
</tbody>
</table>
14 Comment on information to be taken into account in determining applications

Support.

Dairy Australia supports the APVMA considering certain information provided during an assessment period and its impact on registration timelines. This particularly applies to longer term (12-36 month) real time stability studies, the results of which could be reviewed later in the assessment period than short term (6-12 month) real time and accelerated stability studies.

15 Comment on computerised decision-making

Support in principle.

Opportunity for reconsideration or review should be provided for applicants.

16 Comment on voluntary recalls

Dairy Australia questions the merit of this proposal as there are no risks from the continued supply and use of products involved in a voluntary recall (by definition).

17 Comment on notification of new information

No comment

18 Comment on standards for registered chemical products

Do not support.

Dairy Australia understands the need to take-action where a product varies from what is approved. However prescribing standards for ranges of constituents in chemical products is likely to create a range of new issues where existing constituents may not meet the default ranges in the new Standard, or changes allowed under the proposal result in changes to the product’s properties (stability, efficacy, usability or safety).

Creating and maintaining the large number of ‘standards’ to cater for the different constituents would appear to be a large body of work. APVMA’s resources may be better directed to reducing the costs and timeframes of registering products.

19 Comment on suspensions or cancellation of approvals and registrations for providing false or misleading information

No comment

20 Comment on addressing an inconsistency in label particulars (supply with unapproved label)

No comment

21 Comment on variation of approval or registration during suspension

No comment

22 Comment on prescribing matters for the statutory criteria

No comment

23 Comment on removing the need for an annual operational plan

No comment
24 Comment on aligning the 2014 legislation review with the current review of agvet chemical legislation

No comment

25 Comment on other minor and machinery changes to the Agvet Code and the Administration Act

No comment

26 Comment on other amendments from the Agriculture and Water Resources Legislation Amendment Bill 2016

No comment

27 Comment on other minor and machinery changes to the Agvet Code and the Administration Act

No comment

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

No comment

→ Go to section H

Section G: Long-form response to the consultation paper

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

References provided under the proposal comments
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) ________________________________

Date (dd/mm/yyyy) ________________________________

Full name ________________________________

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.

Personal information may be published on the department’s website, disclosed to other Australian agencies, persons or organisations where necessary for these purposes, provided the disclosure is consistent with relevant laws, in particular the Privacy Act 1988. Your personal information will be used and stored in accordance with the Privacy Principles.

See the department’s Privacy Policy to learn more about accessing or correcting personal information or making a complaint. Alternatively, telephone the department on +61 2 6272 3933.