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.

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) Horticulture Innovation Australia Limited

2 Contact address

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Suburb/town/city Sydney State/territory NSW Postcode 2000
3 Contact person

Given name(s) David______________________ Family name Moore_____________________
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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

Hort Innovation believes there is merit in exploring the concept of provisional registrations, with regard to its application to new compounds, i.e., new chemistries or new modes of action, being brought to market. Adopting such an approach should provide an opportunity for many minor crops to be included on labels of the new compounds at the time of first registration, thereby reducing the need for many subsequent off-label permits.

The consultation paper indicates that the period of provisional registration would be no more than three years and that limits on the use of efficacy data could be imposed. However, for many new chemistries or compounds with new modes of action it is likely that the periods of patent protection would still apply, in which case there may be little incentive for a registrant to seek provisional registrations. Hort Innovation also suggests there could be value in linking provisional registrations to Proposal 4 with regards to extending limits on use of information for new compounds, i.e., in addition to the 10 years currently granted from first registration.

Hort Innovation suggests that consideration be given to broadening the scope under which provisional registration could be granted, i.e., to include other elements in addition to efficacy. The submission of data associated with crop safety and residues could also be considered as part of a provisional registration scheme, as this would more likely promote the inclusion of many minor crops onto labels at the time of first registration. In many minor crop situations, the lack of residue data is often the more significant hurdle to gaining a regulatory approval. As with efficacy, as is currently the situation with minor use permits for many uses, residues and crop safety can be extrapolated from use in related or similar crops from other jurisdictions. Therefore, there would be value in considering such an expansion provided the available information was sufficient to satisfy the APVMA that any risks were acceptable and manageable.

Hort Innovation is uncertain that such an approach could operate successfully in situations where there are multiple registrants for an existing compound. Firstly, Hort Innovation is concerned that if provisional registrations could be granted to more than one registrant for the same use concurrently, there would be little incentive for registrants to participate as there would, in effect, be no exclusivity. Secondly, there could be scope for ‘free riding’ in that a second registrant could seek provisional registration at a time after a first registrant with the intention to image the label of the first once any period of exclusivity had expired. Further, as indicated in the consultation paper there is a risk of devaluing any investment in data generation by registrants without provisional registrations, i.e., where a registrant seeks registration based on the submission of data where another one registrant holds a provisional registration for the same use.

In terms of the time to provide data Hort Innovation thinks three years to generate and supply data for assessment and finalisation should be sufficient. However, it would be appropriate that there be scope for the granting of extensions in the event of unforeseen circumstances impacting the ability of a registrant to provide the necessary data.

Hort Innovation has no preference on whether provisional registrations should be ‘offered’ by the APVMA or subject to registrants seeking such approvals. However, Hort Innovation does believe that should provisional registrations be adopted, there should be an opportunity for stakeholder comment.
11 Comment on accreditation of assessors

Hort Innovation is unsure how instigating a system of accredited efficacy assessors would increase efficiency in application processing and timeframes particularly as issues relating to crop safety are still to be addressed internally by the APVMA. Further efficacy assessment timeframes are shorter than those currently required for assessing other scientific areas such as residues and as a result would be unlikely to be the limiting step in the finalisation of a registration application. Hort Innovation however acknowledges that should constraints exist with respect to the available pool of efficacy assessors, the availability of independent certified assessors could be of benefit.

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

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

Hort Innovation welcomes DAWR initiating a discussion on incentives and believes this to be a positive step and believes that for new chemistries the benefits of longer limitation and protection periods would be attractive to registrants, i.e., outweigh any costs. From a minor crop perspective Hort Innovation believes implementing such an approach would increase the potential for greater access through label extensions on new pesticide labels.

In terms of the proposed extensions to limitation and protection periods Hort Innovation would encourage DAWR to review the minor use incentive provisions of the regulations associated with the Canadian Pest Control Products Act (http://laws-lois.justice.gc.ca/eng/acts/P-9.01/). As with the current limitation and protection periods under 34M of the Agvet Code in Australia, the exclusive protection period in Canada is 10 years from the date of first registration. However, that protection can be extended by one year for each three eligible minor use crops added to a label, up to a maximum of five additional years (Regulations Amending the Pest Control Products Regulations). In seeking the additional years of exclusive protection, a Canadian registrant application must provide evidence of support from users and federal and provincial agriculture authorities and the minor uses would, generally, have been part of the Canadian minor use priority list. The extensions only apply to residue data and apply only to the crops tested. If representative crops are tested the maximum number of eligible minor uses in the crop group will be the number of representative crops. If such a system were to apply in Australia and a registrant sought to gain extended data protection by seeking to register in Assorted Tropical and sub-Tropical crops, which contains 39 crops, doing
residue trials in avocados, bananas and mangoes, they would gain one additional year as these are the three representative crops for the crop group.

Hort Innovation feels that possible extensions to protection periods should be coupled with additional registrant incentives such as fee waivers and discounts, particularly where generic compounds are involved. In Canada, the fees for a residue data assessment can be $15,838 with a processing fee of $1,133. In the Canadian regulations a user requested minor use label expansion (URMULE*) is exempt other than a processing fee of $247. Under this approach, an application would not be charged a fee if the proposed label extension fell within the URMULE category. The registrant would pay a relatively small processing fee for the label change. From an Australian perspective such an approach would be of great value particularly when as it would lessen the cost for situations involving individual crops or where data protection extensions may be considered of little commercial value to registrants, e.g., use of generic compounds in minor crops.


14 Comment on information to be taken into account in determining applications

15 Comment on computerised decision-making
16 Comment on voluntary recalls

17 Comment on notification of new information

18 Comment on standards for registered chemical products

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

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

21 Comment on variation of approval or registration during suspension
22 Comment on prescribing matters for the statutory criteria

23 Comment on removing the need for an annual operational plan

24 Comment on aligning the 2014 legislation review with the current review of agvet chemical legislation

25 Comment on other minor and machinery changes to the Agvet Code and the Administration Act
26 Comment on other amendments from the Agriculture and Water Resources Legislation Amendment Bill 2016

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

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

→ Go to section H

Section G: Long-form response to the consultation paper

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

Date (dd/mm/yyyy) 31/07/2018

Full name David Moore

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.

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