Dear Madam/Sir

Accord is pleased to provide comments on the Department’s efforts to improve the operational efficiency of the APVMA through its consultation on the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 (Draft Bill).

Accord is the peak national industry association representing the manufacturers and marketers of formulated hygiene, cosmetic and specialty products, their raw material suppliers, and service providers. Accord member companies make and/or market fast-moving consumer and commercial goods including hygiene, cosmetics and specialty products, sunscreens, food contact sanitisers, industrial and agricultural sanitisers, household pesticides, disinfectants and specialty commercial products. Member companies include large global consumer product manufacturers as well as small dynamic Australian-owned businesses with 52\(^1\) percent of members operating as SME (<200 employees). A list of Accord member companies is available on our website: http://accord.asn.au/about/members.

Approximately 23\(^2\) percent of our members have dealings with the APVMA. Most of which are small to medium enterprises operating in low margin businesses that are susceptible to input cost-pressures. Products are either fast moving, low risk consumer goods or low risk, well characterised products which represent a low regulatory burden on the agvet sector and are not the core focus of the APVMA’s regulatory activities.

Accord members have an interest in the efficient and effective operation of the APVMA in the administration of its legislation including implementation of reform initiatives. As the ANAO audit\(^3\) found, there is room for improvement. Accord has for many years been attempting to introduce reform to the regulation of dairy sanitisers. Despite the APVMA receiving budget funding for reform to low risk products Accord has not seen anything meaningful by way of reform. Accord was presented with a Draft of the Agricultural and Veterinary Chemicals Code (Listed Chemical Product – Dairy sanitisers and cleansers) Standard in September 2016, but this fell far short of industry expectations for reform.

The development of the Standard was not undertaken in consultation with industry. The result was poor. Industry and APVMA should work collaboratively along with departmental policy staff with responsibility for reducing the regulatory burden on industry, to achieve meaningful reform which can be implemented by industry.

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\(^1\) Results from Accord Industry Size and Scale Survey 2016
\(^2\) ibid
\(^3\) ANAO Report No. 56 2016-17 Pesticide and Veterinary Medicine Regulatory Reform Australia Pesticides and Veterinary Medicines Authority
Accord members continue to seek the development of a standard for dairy sanitisers modelled on the NZ group standards approach under Section 6E of the Agvet Code. We welcome the opportunity to meet with departmental officers to further develop the reform option.

In general, Accord is supportive of the proposed measures, although we note that they are of a minor nature. Our comments and/or support for the proposals relevant to Accord’s membership is attached.

Please do not hesitate to contact me on 02 9281 2322 or at dsabic@accord.asn.au should you have any questions in relation to Accord’s submission.

Yours sincerely

Authorised for electronic transmission

Dusanka Sabic

**Director, Regulatory Reform**

21 July 2017
Proposal 1 – Clarifying confidential commercial information (CCI) provision
Supported – It is noted that this proposal should reduce the uncertainty for APVMA staff regarding CCI disclosure, however this possibly could have been addressed through appropriate administrative arrangements such as development of clear policy guidelines and standard operating procedures. The use of CCI requires ongoing monitoring to ensure that even with the proposed changes that no unintended disclosure of CCI occurs and that CCI remains protected within a lighter touch regulatory environment.

Proposal 2 – Simplifying reporting requirements for annual returns
Supported

Proposal 3 – Increase the APVMA’s flexibility to manage minor errors in applications at the preliminary stage
Supported

Proposal 4 – APVMA amendment of the relevant particulars or conditions in a variation application
Supported

Proposal 6 – Enable a person to apply to vary the particulars of a label approval that is suspended
Supported

Proposal 7 – Amend the definition of ‘expiry date’
Supported

Proposal 8 – Add antimicrobial resistance as a specific safety consideration
Not supported. This appears to be a very specific requirement for a very small group of products. While Accord recognises that antimicrobial resistance is a growing global concern, indeed the Communique from the recent G20 Forum of 7-8 July referred to global actions to tackle antimicrobial resistance. The aim is to restrict the use of antibiotics through responsible and prudent use. We do not consider that any one safety criteria should be given greater consideration than other safety factors and that appropriate risk analysis and management for the entire product lifecycle should occur. If this proceeds, then the scope of application needs to be clearly defined to avoid products which are not the target of the requirement to be inadvertently caught up.

Proposal 9 – Including civil penalty provisions for false or misleading information
Supported but any additional provisions should be consistent with the Government’s Regulatory Powers (Standard Provisions) Act 2014 (RPSPA) which provides the framework for standard regulatory powers to be exercised by agencies across the Commonwealth. The key features of the RPSPA include standard provisions in relation to monitoring and investigation powers, as well as enforcement provisions using civil penalties, infringement notices, enforceable undertakings and injunctions. Implementation of the RPSPA supports the Government’s regulatory reform agenda as it simplifies and streamlines Commonwealth regulatory powers. We understand that the provisions in the Biosecurity Act 2015 are based on the RPSPA and therefore Accord’s recommendation is not inconsistent with the intent of this reform. We support the uniform adoption of the RPSPA by all Commonwealth entities with a regulatory function and support consistency of the Agvet Code provisions with the RPSPA.

Proposal 10 – Minor technical amendments to the Administration Act and Agvet Code
Supported