accord
hygiene, cosmetic & specialty products industry

Committee Secretary
Senate Standing Committee on Rural and Regional Affairs and Transport
PO Box 6100
Parliament House
CANBERRA ACT 2601

email: rrat.sen@alp.gov.au

E-MAILED

Dear Madam/Sir

Please find Accord's submission to the Senate Standing Committee on Rural and Regional Affairs and Transport inquiry into the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014 (the Amendment Bill).*

Accord Australasia, represents the manufacturers and suppliers of formulated products, including: hygiene, cosmetics and specialty products – those relevant to this inquiry include: personal insect repellants with sunscreens, food contact sanitisers, household pesticides, disinfectants including dairy cleansers and sanitisers and, specialty commercial products. These products help safeguard public health and enhance our quality of life.

The economic and social footprint of our sector and member businesses is as follows (a current member list is at Attachment 1):

- Annual retail level sales across the sector nudging $10 billion
- Accord's membership is 100 companies
- Collectively, our members employ more than 12,000 full-time equivalent positions nationally
- Accord members operate over 180 offices nationally and more than 66 manufacturing sites
- Through Accord, member businesses support the following programs, which assist the community: Look Good…Feel Better cancer patients support service, Hygiene for Health education website, What's in it? Ingredient disclosure program for household cleaning products, Recognised™ Environmental Credentials Scheme for commercial cleaning products, and WashWise laundry sustainability website and the Furphies website which tackles unfounded scares about our industry's products and ingredients.

Ours is a heavily regulated industry, as recognised by the Productivity Commission (PC) in its 2008 report into chemicals and plastics regulation. Accord supports independent, science-based regulation where warranted for legitimate public health and environmental risks but, consistent with the PC report recommendations, believes Australia's overly complex and fragmented regulatory system for chemicals management and the costs associated with this regulation needs urgent and significant overhauling.

Accord members have a specific and direct interest in the agvet reform process currently underway. Approximately 40% of Accord members have an interaction with the Australian Pesticides and Veterinary Medicines Authority (APVMA). The majority are small to medium enterprises operating in low margin businesses that are susceptible to input cost-pressures. The majority of products are either fast moving low risk consumer goods or low risk, well characterised products which should represent a low regulatory burden on the agvet sector and are certainly not the core focus of the APVMA's regulatory activities.

Accord supports the Amendment Bill as it delivers on the Coalitions' pre-election promise to reduce the red tape burden on the agvet sector and in particular, the removal of the unnecessary re-registration and re-approval processes. It also implements many of the reforms commenced by the previous government

to increase the efficiency and effectiveness of the regulatory agency, the APVMA. There should be bi-partisan support for the reform measures contained in the Amendment Bill.

Many of the reforms proposed will have a direct benefit to small and medium enterprises.

Accord's comments in relation to the Amendment Bill's proposed changes are at Attachment 2. We also put forward some additional reform proposals for the Senate Committee's consideration.

Accord also supports the views put forward by our sister association CropLife Australia.

Yours sincerely

Bronwyn Capanna
Executive Director

April 2014

ATTACHMENT 1

Members

Consumer, Cosmetic and Personal Care

Advanced Skin Technology Pty Ltd
Amway of Australia Pty Ltd
Apisant Pty Ltd
AVON Products Pty Limited
Beautiworx Australia Pty Ltd
Beautopia Hair & Beauty Pty Ltd
Beiersdorf Australia Ltd
BrandPoint Pty Ltd
Chanel Australia
Clorox Australia Pty Ltd
Colgate-Palmolive Pty Ltd
Combe Asia-Pacific Pty Ltd
Conair Australia Pty Ltd
Cosmax Prestige Brands Australia Pty Ltd
Coty Australia Pty Limited
De Lorenzo Hair & Cosmetic Research Pty Ltd
Elizabeth Arden Australia
Emeis Cosmetics Pty Ltd
Energizer Australia Pty Ltd
Estée Lauder Australia
Evolve Hair Concepts Pty Ltd
Frostbland Pty Ltd
GlaxoSmithKline Consumer Healthcare
Helios Health & Beauty Pty Ltd
iNova Pharmaceuticals – A Valeant Company
Integria Healthcare (Aus) Pty Ltd
International Beauty Supplies Pty Ltd
Johnson & Johnson Pacific
KAO Australia Pty Ltd
KAO Brands Australia Pty Ltd
Keune Australia
Kimberly-Clark Australia
La Biosthetique Australia
La Prairie Group
L'OCCITANE Australia Pty Ltd
L'Oréal Australia Pty Ltd
LVMH Perfumes and Cosmetics
Mary Kay Cosmetics Pty Ltd
Natural Australian Kulture Pty Ltd
Nutrimetics Australia
NYX Pty Ltd
Panamex Group
Procter & Gamble Australia Pty Ltd
PZ Cussons Australia Pty Ltd
Reckitt Benckiser
Revlon Australia
SC Johnson & Son Pty Ltd
Scental Pacific Pty Ltd
Shiseido (Australia) Pty Ltd
Syndet Works Pty Ltd
The Heat Group Pty Ltd
The Purist Company Pty Ltd
Three Six Five Pty Ltd
Trimex Pty Ltd
True Solutions International Pty Limited
Ultraceuticals
Unilever Australasia
Vitafive
Weleda Australia Pty Ltd

Hygiene and Specialty Products

Albright & Wilson (Aust) Ltd
Antaria Limited
BP Castrol Australia Pty Ltd
Brenntag Australia Pty Ltd
Castle Chemicals Pty Ltd
Chemetall (Australasia) Pty Ltd
Clariant (Australia) Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
Ecolab Pty Limited
Huntsman Corporation Australia Pty Ltd
Jalco Group Pty Limited
Jet Technologies Australia Pty Ltd
Lab 6 Pty Ltd
Novozymes Australia Pty Ltd
Nowra Chemical Manufacturers Pty Ltd
Peerless JAL Pty Ltd
Recochem Inc
Rohm and Haas Australia Pty Ltd
Solvay Interox Pty Ltd
Sopura Australia Pty Ltd
Tasman Chemicals Pty Ltd
Thor Specialties Pty Limited
True Blue Chemicals Pty Ltd
Univar Australia Pty Ltd
Whiteley Corporation Pty Ltd

Associate Members

Corporate Travel Services

Unique Group Travel

Graphic Design and Creative

Ident Pty Ltd

Legal and Business Management

FCB Lawyers

K&L Gates

KPMG

TressCox Lawyers

Regulatory and Technical Consultants

Clare Martin & Associates Pty Ltd

Competitive Advantage

Engel, Hellyer & Partners Pty Ltd

Robert Forbes & Associates

Seren Consulting Pty Ltd

Sue Akeroyd & Associates

Toxikos Pty Ltd

Specialist Laboratories and Testing

ams Laboratories

Dermatest Pty Ltd

Feb 2014

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ATTACHMENT 2

Implementing the election commitment to remove re-registration

Re-approval and re-registration would apply substantial increases in the regulatory burden on applicants, registrants and approval holders. This would increase the total administrative and regulatory costs of the registration system without providing any meaningful improvement in human health, safety or environmental protection. As the APVMA is a fully cost recovered entity this would further disadvantage Australian industry through reduced productivity and higher cost burden.

No cost benefit analysis or any other evidence has been presented before or since the original introduction of these measures to demonstrate that this reform would deliver any net benefit. Accord had previously, through other consultations, raised our concerns that the proposed reforms arising from the Better Regulation Ministerial Partnership Review will not be delivered through the then Agricultural and Veterinary Chemicals Legislation Amendment Bill. The Amendment introduced an unnecessary regulatory burden on industry through the introduction of the mandatory re-approval and re-registration process. We support the measures in the Amendment Bill to remove this aspect of the agvet legislation.

Reducing red-tape by allowing for less frequent renewal registrations

Accord Members questioned whether this proposal would achieve any significant reform given the way the APVMA's cost recovery process operates with regard to product registration and the levy calculated on product sales. It was felt that further discussion was required to explore whether any tangible benefits could be derived. Members' views were divided as to whether they would take up this option if it were introduced. However, if this was to be introduced then members would prefer to have as much flexibility as possible in allowing choice between annual or multiple year renewals. Members do not want to lose the option of annual registrations. We are unsure as to why the annual renewal option should carry a premium as this would be status quo. This appears to be a reform initiative which may be of little value to industry, indeed may be more costly to industry but may allow the APVMA some administrative efficiency, although this is questionable without any impact assessment. Industry would not support any such change, as reform should deliver benefits to both the regulator and the regulated sector.

Addressing concerns with chemical product quality

Accord is supportive of amendments that provide meaningful improvements in human health, safety or environmental protection under s99. This amendment provides the APVMA with the tools to address any issue of concern regarding the safety and quality of products and can be utilised more efficiently than the proposed re-approval and re-registration, which is a cumbersome process. The power is to apply if the APVMA considers the information is necessary to protect human, animal and environmental health and safety or protect trade.

Improving the APVMA's compliance toolkit will enable it to more effectively deploy its monitoring, compliance and enforcement resources on those individuals and organisations that present the greatest risk. It will therefore be able to respond more effectively to consumer concerns in a timely manner than the proposed re-registration process which could take some 4 years to complete.

Accord members' only concern with this expansive power under s99 is that the APVMA use it judiciously.

Reducing red-tape by allowing for simpler variations to approvals and registration

Industry supports the introduction of this amendment and looks forward to working with the Department of Agriculture and the APVMA as to what kinds of variations would be permitted. We note that the introduction of a notification-only system for simple variations would further reduce red-tape and costs on industry. Industry would regard label changes, repacks and formulae changes within prescribed limits as examples of variations which could be notified.

A recent example is of an Accord member having difficulty making even minor label changes to a repack, where the use pattern is the same. The aim of the change is to enhance the clarity of instructions and the

change is minor. This has proven extremely difficult to do under the current legislative requirements and will incur costs and lengthy delays.

Reducing red-tape by no longer requiring annual returns about active constituents
Supported – this is a welcome measure.

Improving efficiency by requiring electronic lodgement of information and fees
Supported – this is a welcome measure.

Obliging access to information about chemicals that the APVMA holds
Supported – this is a welcome measure.

Further matters which the Senate Committee could take into consideration are as follows:

Legislative requirement for minimum effective regulation
Any reform to the agvet regulatory environment must be done within a proper risk management control framework. We therefore welcome the emphasis on decision-making using a risk management framework. However, the risk appetite for regulators differs considerably to that of industry. It has been Accord's experience that regulatory agencies have had limited success in implementing reform measures targeting the lower risk spectrum. This was also identified by the PC report which cited examples of failed reform measures, as well as noting that Australian regulatory agencies are inherently conservative.

It is therefore essential that the legislation includes a mandatory requirement that within the APVMA's risk management framework in coming to a decision, it must choose the regulatory option which has the **least regulatory burden and cost impact on industry**. Industry supports such minimum effective regulation.

The agvet framework needs to be seamlessly integrated with other chemical control mechanisms in operation. The agvet reforms as part of the Government's overall commitment to reform provides an opportunity to improve the efficiency of the agvet sector through optimising existing regulatory controls, in line with the PC's findings and recommended actions for agvet chemicals.

Therefore, to ensure successful implementation of such a measure, a number of steps must be taken such as separation of scientific assessment and risk assessment from risk management; adequate training for staff; identification of a reform champion, establishment of a credible independent expert body to make risk management decisions; and continued political support for reform.

In Accord's previous submissions on improving the efficiency and effectiveness of the regulatory environment for the agvet sector, we have consistently supported the development of an appropriate risk management framework to take into account all levels of risk within the APVMA's regulatory jurisdiction. We have noted that the ANAO audits of the APVMA in 1997-98 and 2006 recommended that risk management in the agvet sector required improvement, particularly in the area regarding appropriate allocation of resources for low risk products. The Government's intention to implement an appropriate risk management framework being long overdue is therefore greatly welcomed. However, it requires considerable industry input and the process to date regarding early industry input and consultation on the development of APVMA regulatory guidelines has been poor to say the least.

Enhancing risk management capabilities
Of key concern to Accord members is the development of an appropriate risk management framework which recognises products of low regulatory concern and provide the appropriate controls to manage those risks. Accord notes that new provisions are intended to allow the APVMA to only consider trade and efficacy risks associated with agricultural chemical products in circumstances where it is relevant to the product being assessed. We see no reason why the discretion could not be extended to all other matters

with which the APVMA must be satisfied and not just trade and efficacy. This would then enable the APVMA to accept self-assessment for certain classes of product based on agreed criteria.

Further, it should be mandated that when the APVMA considers matters with regard to granting or refusing an application that the APVMA must also apply the least burdensome regulatory requirements to adequately protect against the products' risk. This is not unique as it is currently a requirement for the US Environmental Protection Agency (EPA) under its Toxic Substances Control Act (TSCA) and should be adopted in Australia as a matter of course.

The APVMA's risk based management framework should re-allocate its assessment effort commensurate with the level of risk, i.e. minimum effective regulation. Accord's work with the APVMA in developing a lighter regulatory touch for dairy sanitisers under the COAG reform process has led us to believe that this will be a very difficult process unless there is appropriate policy oversight and direction, leading to organisational cultural change.

Future legislation should reference acceptable authorities and entities, decisions, monographs, regulatory tools etc. which are legitimate alternatives to the current registration and assessment process. There is insufficient flexibility within the current structure to adopt decisions from comparable regulatory authorities even within Australia or to develop more efficient processes such as self-assessment as New Zealand has done. Through this process, group standards are developed on the basis of risk and products meeting those risk characteristics must adhere to the controls within the standard. The suite of controls is comprehensive, but subject to industry self-classification. This is one model of risk management for low risk products which is working well in New Zealand and could be considered as a model in Australia. An alternative approach is to adopt a template or master/model registration system. This would allow a company to tailor registration to their needs, whilst providing flexibility.

Clearly there is a need to develop a comprehensive regulatory approach to dealing with low risk products so that the APVMA can deal with more pressing issues. In the policy development phase, suggestions such as adopting an approach similar to that used in the United States which gives preferential assessment timeframes for products which meet predefined hazard criteria was made, yet we can see no reference to how the APVMA might adopt more streamlined approaches based on either overseas experiences or adopting decisions for comparable regulatory agencies.

Industry supports the APVMA's concept of a model or template approach which appears to be similar to that as used in the United States. Alternatively, the model adopted by the TGA for its listed category of products could also be adopted for low risk products which are well characterised and have a safe history of use. More use could be made of industry self-assessment such as for minor changes to product formulation, as should label changes without the need for re-assessment by the APVMA and additional payment of fees.

Cost recovery

Australia is the only advanced economy which operates on a full cost recovery basis for industrial chemicals, therapeutic goods and agricultural and veterinary products. We believe that full cost recovery is a break on innovation, a barrier to trade and stifles competition. The introduction of cost recovery has not led to improved efficiency and effectiveness of the three major regulators with which Accord Members deal; rather it has led to increased costs and reduced outcomes.

In general Accord members supply into the marketplace products which are low risk, well characterised agvet and domestic use products. As such, they require a lower level of regulatory intervention, which should be reflected in the cost recovery arrangements applied by regulatory agencies. In particular there should be a reconsideration of the application of the levy on the turnover of goods sold. In general, many of these low risk products are high volume consumer goods requiring little interaction with the regulator, but nevertheless a levy is still imposed on each and every sale. The application of a flat levy on the sale of

goods amounts to cross subsidisation by low risk products of high risk, high regulatory intervention products and is inconsistent with Government's cost recovery policy.

Accord has been engaged in the Department's review of the APVMA's cost recovery first principles. It is critical that the APVMA's cost recovery processes be amended to better reflect the Government's cost recovery principles particularly in relation to the commercial benefit derived to an individual company and that of the public interest.

Adoption of international standards and assessments

In general Accord believes that there should be greater recognition of approved ingredients by Australian chemical regulators as well as those overseas. For example the APVMA could recognise those ingredients and/or products which have been assessed by the Therapeutic Goods Administration (TGA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Food Standards Australia New Zealand (FSANZ). If ingredients appear on the approved lists or inventories of these agencies then they should be accepted by the APVMA, or as a minimum, not be regarded by the APVMA as new.

Furthermore, the APVMA should also accept the decisions of comparable advanced economy regulators such as the US EPA on ingredients and/or products deemed as low risk. This would allow for timelier introduction of low risk products and would lower costs and make registration processes simpler which would facilitate more small business engagement in the agvet sector.