Committee Secretary
House of Representatives Standing Committee on
Agriculture, Resources, Fisheries and Forestry
PO Box 6021
Parliament House
CANBERRA ACT 2600

email: arff.reps@aph.gov.au

Dear Committee Secretary

Please find following Accord's submission to the inquiry of the House of Representatives Standing committee on Agriculture, Resources, Fisheries and Forestry into the *Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (*the 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, deodorants & fragrances, household pesticides, disinfectants 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 attached):

- Annual retail level sales across the sector nudging $10 billion
- Accord's membership is just under 100 companies
- Collectively, our members employ more than 14,000 full-time equivalent positions nationally
- Accord members operate over 170 offices nationally and more than 50 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 reforms currently being proposed as contained within the Bill. Approximately 40% of Accord members have an interaction with the 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.

We welcome the Committee's inquiry into the Bill. Accord has concerns that the proposed reforms arising from the Better Regulation Ministerial Partnership Review will not be delivered through the Bill. We support the issues raised in CropLife Australia's submission regarding the failure of the Bill to reduce red tape, improve the efficiency and effectiveness of the regulatory system, reduce costs and improve time to market for innovative products. Instead the Bill will introduce an unnecessary regulatory burden on industry e.g. through

the introduction of the mandatory re-approval and re-registration process. In addition, industry is required to pay for this so called reform measure through an additional impost under cost recovery arrangements**.**

Australia's costly, complex and fragmented regulatory system for the management of chemicals is a serious issue for our industry. Members have raised concerns at the very slow pace of reform, the ongoing loss of innovation and business opportunities, as well as continuing problems with the decision making and operational performance of our key regulatory agencies involved in chemicals management.

In previous submissions, Accord has argued for a holistic examination of the regulation of the agvet sector and its products from a national perspective. We note with concern that the work of the Better Regulation Ministerial Partnership did not include consideration of PC Recommendation 8.2 for control of use. Resolution of this issue is critical to the reform agenda for agvet chemicals and will have a significant impact on the overall cost of the regulatory scheme and how it is to be managed and funded. To date, industry has borne the cost of much regulatory reform activity with little to show for it. Industry should not be subjected to any further cost pressures through increased fees and charges resulting from the changed regulatory landscape.

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 continuum 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 Bill 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**.

It has been estimated that these reforms will significantly increase the cost to agricultural chemical producers by as much as 30% each year. In turn, this increase in cost recovery from the industry may have a detrimental effect on the availability of accessible chemicals for Australian production systems. It is therefore essential that industry is a beneficiary of the reform process - the cost increases in the quantum identified are simply not sustainable.

The 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.

While the Government and the Minister for Agriculture are to be congratulated for taking the initiative to progress this reform work, we remain disappointed that little has been done to implement the PC recommendations arising from its work on chemicals and plastics regulation. We recommend that the Government moves quickly to implement reforms of significance to reduce the complexity and inconsistency of the regulatory regime for chemicals in Australia based on the PC's roadmap for reform, i.e. by achieving national uniformity in regulatory areas; by reducing costs and delays in obtaining regulatory approvals; and by attaining economies of scale in regulatory administration.

In considering the package of reforms contained within the Bill, Accord seeks to confirm that there is a net benefit to registrants of agricultural chemical products. We remain concerned that the efficiency benefits expected will not accrue. On the basis of past experience, there is a very real concern that these reforms will increase rather than decrease the current inefficiency of the system. Proper implementation is the key to successful reform and industry needs to be fully engaged in the development of implementation strategies if real change is to be achieved.

Consistent with our advice to the Better Regulation Ministerial Partnership Review of NICNAS, Accord notes that under the new national Work Health and Safety Acts, all workplaces must conduct a workplace risk assessment for all hazardous chemicals found on that workplace. This duplicates and is to some extent inconsistent with the pre-market risk assessment conducted by the APVMA. Consequently, the APVMA's workplace risk assessments are now largely redundant with limited regulatory impact or effect. Rationalising OHS assessments for both industrial and agvet chemicals would reduce some of the duplication and complexity which the PC noted was at the core of issues faced by the chemicals and plastics sector.

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.

1 Initial assessment and registration processes

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.

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 intervention products and is inconsistent with Government's cost recovery policy.

The APVMA's risk based management framework should re-allocate its assessment effort commensurate with the level of risk. 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.

The Bill 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 of risk. This is one model of risk management for low risk products which is working well in New Zealand and should be seriously considered as a model in Australia.

Cleary 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 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.

While we note that the Bill has introduced a streamlined approach to listed registration for products of low regulatory concern, we do not believe that the streamlining has been sufficient to make it an attractive option for industry to pursue.

2 Re-approvals and re-registration

Accord does not accept that the current regulatory system is in need of a mandatory scheme for the re-registration or continuation of approvals for active constituents and registering of chemical products. Australia as a net importer of goods, should leverage off similar work currently being undertaken by comparable advanced economies rather than duplicate effort. In this area, the current proposal will only introduce more uncertainty into the market and provide less predictability while increasing costs. This proposal will not meet the general aim of the reform to encourage the development of modern and safer chemicals through cutting unnecessary red tape.

This proposal is not reform, it will add red tape to an already complex system and will drive down innovation. Accord's view is that the existing chemicals review process needs to be more efficient and effective rather than introducing a new layer of bureaucracy and potentially leaving certain decisions regarding defining contemporary standards for existing products to the discretion of a few individuals. As part of the COAG principles for regulatory best practice, good regulation minimises the exercise of bureaucratic discretion. In this case it must not be allowed to play a part in determining safety concern for existing products, and must be subject to rigorous independent scientific scrutiny.

3 International comparisons and trade issues, including effect on small companies

As mentioned above, the New Zealand Environmental Protection Agency (EPA) manages low and medium risk products with similar hazard classifications through the adoption of a Group Standard. The Group Standard contains all the controls required for managing a class of products with a similar hazard profile and includes such matters as storage and handling, transportation, and labelling. Companies self-assess against the Group Standard hazard classification for their particular products. The NZ EPA has recently commenced developing Group Standards for agvet products. We believe that this is a good example of how products which represent a low regulatory concern can be managed in a pragmatic, low cost way and should be seriously considered as a model to be adopted in Australia. In addition, the APVMA should

mutually recognise products from NZ which are regulated under these controls rather than requiring registration. Two examples are provided for the Committee's information:

- Agricultural Compounds Special Circumstances

The Agricultural Compounds Special Circumstances group standard is for agricultural compounds (i.e. plant protection products or veterinary medicines) that are for use in specific, restricted situations, as detailed in the scope of the group standard. More information can be found on the NZ EPA's website at: http://www.epa.govt.nz/hazardous-substances/approvals/group-standards/Pages/Agricultural-compounds-special-circumstances.aspx

- Animal nutritional and animal care products group standard

The animal nutritional and animal care products group standard is for products intended for administration to an animal to achieve a nutritional benefit, and products used in the external care or grooming of an animal. More information this Group Standard can be found on the NZ EPA website at: http://www.epa.govt.nz/hazardous-substances/approvals/group-standards/Pages/animal-nutrition-care.aspx

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 small business engagement in the agvet sector. Two examples of efforts by the US Government are as follows:

- Generally Recognized as Safe (GRAS)

"GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. In addition to its mandate under FIFRA, EPA has authority to regulate pesticide products under the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 408 of FFDCA authorizes EPA to establish tolerances or safe levels of pesticide residues in raw agricultural commodities; section 409 similarly authorizes EPA to issue food additive regulations for pesticide residues in processed foods. Prior to the establishment of the EPA, the Food and Drug Administration (FDA) had the responsibility for establishing tolerances and food additive regulations for pesticide residues. More information can be found on the US FDA website at: . http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/default.htm.

- Pesticides; Revisions to Minimum Risk Exemption

In addition US EPA is proposing to more clearly describe the active and inert ingredients permitted in products eligible for the exemption from regulation for minimum risk pesticides. EPA is proposing to reorganize these lists with a focus on clarity and transparency by adding specific chemical identifiers. The identifiers would make it clearer to manufacturers; the public; and Federal, state, and tribal inspectors which ingredients are permitted in minimum risk pesticide products. EPA is also proposing to modify the label requirements in the exemption to require the use of specific common chemical names

in lists of ingredients on minimum risk pesticide product labels, and to require producer contact information on the label. Once final, these proposed changes would maintain the availability of minimum risk pesticide products while providing more consistent information for consumers, clearer regulations for producers, and easier identification by states, tribes and EPA as to whether a product is in compliance with the exemption.

More information on this reform activity can be found at https://s3.amazonaws.com/public-inspection.federalregister.gov/201231188.pdf?utm_source=BPIA+Government+Affairs+Committee+January+2nd%2C+2013&utm_campaign=Government+Affairs+Connections&utm_medium=email

These are just a few examples of where similar jurisdictions recognise that low risk products require an alternative regulatory pathway which recognises their risk profile. This situation does not exist in Australia and while the new Bill purports to do this through emphasis on risk management we believe that this should be strengthened with specific statements regarding the treatment of low risk products i.e. as previously mentioned above a statement to the following effect should be inserted into the Bill:

> *It is therefore essential that the Bill 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.*

Furthermore in Accord's submission on the Exposure Draft we also made the comments in relation to international practices which the APVMA could adopt. We attach our submission for the Committee's information.

4 Consultation

The Department of Agriculture, Fisheries and Forestry has undertaken extensive consultation and in general has conducted the stakeholder engagement process quite well. The problem for industry has been that this significant review for the agvet sector has occurred alongside other significant reviews such as for industrial chemicals, therapeutic goods, cost recovery which is in addition to an already heavy workload which businesses and industry associations are already struggling to manage. In particular the rush to meet the Government's commitment to the Seamless National Economy by 31 December 2012 meant that industry was flooded with a wave of consultations towards the end of 2012 which made it difficult to give all matters serious attention.

The area of stakeholder engagement which was missing throughout this process however was detailed advice as to why industry suggestions for reform have not been accepted. While a number of modifications were made to the Exposure Bill in light of stakeholder feedback, it is not known why certain recommendations have not been taken up. This feedback loop should be a mandatory part of any stakeholder engagement process.

The policy officer for this matter is Ms Dusanka Sabic, Accord's Director of Regulatory Reform. Ms Sabic can be contacted on or by email at should you require any further clarification on the matters raised.

Yours sincerely

Bronwyn Capanna
Executive Director

18 January 2013

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
Beiersdorf Australia Ltd
BrandPoint Pty Ltd
Chanel Australia
Clorox Australia Pty Ltd
Colgate-Palmolive Pty Ltd
Combe Asia-Pacific 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
Frostbland Pty Ltd
GlaxoSmithKline Consumer Healthcare
Helios Health & Beauty Pty Ltd
iNova Pharmaceuticals – A Valeant Company
Johnson & Johnson Pacific
KAO Australia Pty Ltd
KAO Brands Australia Pty Ltd
Keune Australia
Kimberly-Clark Australia
La Biosthetique Australia
La Prairie Group
L'Oréal Australia Pty Ltd
LVMH Perfumes and Cosmetics
Mary Kay Cosmetics Pty Ltd
Natural Australian Kulture Pty Ltd
Nutrimetics Australia
NYX Pty Ltd
Procter & Gamble Australia Pty Ltd
PZ Cussons Australia Pty Ltd
Reckitt Benckiser
Revlon Australia
Rusk Australia
SC Johnson & Son Pty Ltd
Scental Pacific Pty Ltd
Shiseido (Australia) 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
Weleda Australia Pty Ltd

Hygiene and Specialty Products

Albright & Wilson (Aust) Ltd
Antaria Limited
Applied Australia Pty Ltd
BP Castrol Australia Pty Ltd
Brenntag Australia Pty Ltd
Callington Haven Pty Ltd
Campbell Brothers Limited
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
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

Equipment and Packaging Suppliers

HydroNova Australia NZ Pty Ltd

Megara (Aust.) Pty Ltd

SCHÜTZ DSL (Australia) Pty Ltd

Graphic Design and Creative

Ident Pty Ltd

Legal and Business Management

FCB Lawyers

KPMG

Middletons

TressCox Lawyers

Regulatory and Technical Consultants

Archer Emery & Associates

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

Silliker Australia Pty Ltd

November 2012

accord
hygiene, cosmetic & specialty products industry

Mr Matt Koval
Assistant Secretary
Agvet Chemicals and Farm Leadership Programs Branch
Department of Agriculture, Fisheries and Forestry, Canberra
GPO Box 858
CANBERRA ACT 2601

Email: agvetreform@daff.gov.au

Dear Mr Koval

Please find following Accord's comments on the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011 (Draft Exposure Bill) as well as more general comments on the agvet reform process.

Accord Australasia, represents the manufacturers and suppliers of formulated products, including: hygiene, cosmetics and specialty products, sunscreens, food contact sanitisers, deodorants & fragrances, household pesticides, disinfectants, feminine hygiene products, specialty commercial products and oral hygiene products. These products help safeguard public health and enhance our quality of life.

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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 reforms currently being proposed as contained within the Draft Exposure Bill.

Approximately 40% of Accord members have an interface with the 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 represent a low regulatory burden on the agvet sector and are not the core focus of the APVMA's regulatory activities. An Accord member perception survey undertaken in 2010 on the performance of the three regulatory agencies, with which they deal, i.e. the Therapeutic Goods Administration (TGA), that National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Australian Pesticides and Veterinary Medicines Authority (APVMA,) indicated a high level of dissatisfaction with the performance of all three agencies. We therefore welcome the Government's consideration of reform to this sector, in particular, its consideration of the adoption of an appropriate risk management framework for low risk products and improvements to administrative processes.

Australia's costly, complex and fragmented regulatory system for the management of chemicals is of concern to our industry. Members have raised concerns at the very slow pace of reform, the ongoing loss of innovation and business opportunities, as well as continuing problems with the decision making and operational performance of our key regulatory agencies involved in chemicals management.

In previous submissions, Accord has argued for a holistic examination of the regulation of the agvet sector and its products from a national perspective. We note with concern that the work of the Better Regulation Ministerial Partnership did not include resolution of PC Recommendation 8.2 for control of use. Resolution of this issue is critical to the reform agenda for agvet chemicals and will have a significant impact on the overall cost of the regulatory scheme and how it is to be managed and funded. To date, industry has borne the cost of much regulatory activity with little to show for it. Industry should not be subjected to any further cost pressures through increased fees and charges resulting from the changed regulatory landscape.

While we welcome consideration of the introduction of a lower level of regulatory intervention for low risk products, we are concerned however, that some of the proposed measures will create additional regulatory controls for which there has been no adequate justification, nor has it been demonstrated that there has been a significant level of market failure which requires regulatory intervention, such as the proposed re-registration continuation scheme.

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 continuum 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 Draft Exposure Bill 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**.

It has been estimated that these reforms will significantly increase the cost to agricultural chemical producers by as much as 30% each year. In turn, this increase in cost recovery from the industry may have a detrimental effect on the availability of accessible chemicals for Australian production systems. It is therefore essential that industry is a beneficiary of the reform process - the cost increases in the quantum identified are simply not sustainable.

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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.

While the Government and the Minister for Agriculture are to be congratulated for taking the initiative to progress this reform work, we remain disappointed that little has been done to implement the PC recommendations arising from its work on chemicals and plastics regulation. We recommend that the Government moves quickly to implement reforms of significance to reduce the complexity and inconsistency of the regulatory regime for chemicals in Australia based on the PC's roadmap for reform, i.e. by achieving national uniformity in some regulatory areas; by reducing costs and delays in obtaining regulatory approvals; and by attaining economies of scale in regulatory administration.

In considering the package of reforms contained within the Draft Exposure Bill, Accord seeks to confirm that there is a net benefit to registrants of agricultural chemical products. We remain concerned that the efficiency benefits expected will not accrue. On the basis of past experience, there is a very real concern that these reforms will increase rather than decrease the current inefficiency of the system. Proper implementation is the key to successful reform and industry needs to be fully engaged in the development of implementation strategies if real change is to be achieved.

Accord's specific comments on the Schedules are at Attachment 2.

The policy officer with responsibility for this matter is Ms Dusanka Sabic, Accord's Director of Regulatory Reform. Ms Sabic can be contacted on 02 9282 2322, 0422569222 or by email at dsabic@accord.asn.au should you require any further clarification on the matters raised.

Yours sincerely

Bronwyn Capanna
Executive Director

March 2012

Members

Consumer, Cosmetic and Personal Care

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Energizer Australia Pty Ltd
Estée Lauder Australia
Frostbland Pty Ltd
GlaxoSmithKline Consumer Healthcare
Helios Health & Beauty Pty Ltd
Johnson & Johnson Pacific
Kao (Australia) Marketing Pty Ltd
Kao Brands Australia Pty Ltd
Keune Australia
Kimberly-Clark Australia
KPSS Australia Pty Ltd
La Biosthetique Australia
La Prairie Group
L'Oréal Australia Pty Ltd
LVMH Perfumes and Cosmetics
Mary Kay Cosmetics Pty Ltd
Natural Australian Kulture Pty Ltd
Nutrimetics Australia
NYX Pty Ltd
Procter & Gamble Australia Pty Ltd
PZ Cussons Australia Pty Ltd
Reckitt Benckiser
Revlon Australia
Sabre Corporation Pty Ltd
Scental Pacific Pty Ltd
Shiseido (Australia) 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
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Competitive Advantage

Engel Hellyer & Partners Pty Ltd

Robert Forbes & Associates

Sue Akeroyd & Associates

Toxikos Pty Ltd

Specialist Laboratories and Testing

ams Laboratories

Dermatest Pty Ltd

Silliker Australia Pty Ltd

August 2011

Comments on Specific Schedules

Schedule 1 – Decision making using a risk-based framework

Accord supports the intent of the proposals contained within items 6, 7, 8 and 9 of *Schedule 1* but this could be further expanded to give greater flexibility and improve efficiencies within the APVMA. Accord notes that these 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.

Consistent with our advice to the Better Regulation Ministerial Partnership Review of NICNAS, Accord notes that under the new national Work Health and Safety Acts, all workplaces must conduct a workplace risk assessment for all hazardous chemicals found on that workplace. This duplicates and is to some extent inconsistent with the pre-market risk assessment conducted by the APVMA. Consequently, the APVMA's workplace risk assessments are now largely redundant with limited regulatory impact or effect. Rationalising OHS assessments for both industrial and agvet chemicals would reduce some of the duplication and complexity which the PC noted was at the core of issues faced by the chemicals and plastics sector.

Accord has in previous submissions recommended the separation of risk assessment and risk management functions for agvet products. We note that the PC, while commenting on the separation of assessment from management for agvet, did not see this as an immediate priority for the APVMA in 2008. We would suggest that the time has now come when these structural issues should be considered. Therefore, in considering the new national risk assessment and risk management agvet entities, we recommend that the PC Recommendation 4.3 should be considered as to whether there are synergies and potential cost savings through the amalgamation of a scientific assessment entity for industrial and agvet chemical assessments. Accord raises this as a point for consideration when looking to the long term future of chemicals management in Australia. In all likelihood, Australia will be faced with a critical shortage of suitably qualified chemists, scientists, agvet and regulatory specialists as well as toxicologist to undertake this work and will have to look at more innovative ways to achieve the same outcomes with less skilled staff. It is critical that we use this reform process to consider workforce planning and its impacts on the proposals under consideration.

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.

In general Accord members supply into the marketplace low risk, well characterised agvet and domestic 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 are levied on each and every sale. The application of a flat levy on the sale of goods amounts to cross subsidisation of low risk products to high risk products and is inconsistent with Government's cost recovery policy.

The APVMA's risk based management framework will re-allocate its assessment effort commensurate with the level of risk. 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.

Scheduled 1 also needs reference to acceptable authorities and entities, decisions, monographs, regulatory tools etc which are acceptable alternatives to the current registration and assessment process. There is not enough flexibility within the current structure to adopt decisions from comparable regulatory authorities even within Australia or to develop 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 of risk. This is one model of risk management for low risk products which is working well in New Zealand and should be seriously considered as a model in Australia.

Cleary 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 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. The PC report recommended features of an effective and efficient chemical assessment scheme in its report into chemical and plastics regulation (Box 4.2 (p60). Accord recommends these be the basis for developing an appropriate risk management framework for agvet chemicals.

PC Recommendation 8.1 should be adopted as a matter of course. Accord is not certain that the limited changes reflected in Schedule 1 will deliver an appropriate risk management framework for the ongoing assessment and registration of low risk products.

Schedule 2 – Continuation of approvals, registrations and listed registrations

Accord does not accept that the current regulatory system is in need of a mandatory scheme for the re-registration or continuation of approvals for active constituents and registering of chemical products. Australia is generally regarded as a 'policy taker' and as such, should leverage off similar work currently being undertaken by comparable advanced economies rather duplicate effort. In this area, the proposal as such will only introduce more uncertainty into the market and provide less predictability while increasing costs. This proposal will not meet the general aim of the reform to encourage the development of modern and safer chemicals through cutting unnecessary red tape. This proposal is not reform, it will add red tape to an already complex system and will drive down innovation. Accord's view is that the existing chemicals review process needs to be more efficient and effective rather than introducing a new layer of bureaucracy and potentially leaving certain decisions regarding defining

contemporary standards for existing products to the discretion of some individuals. As part of the COAG principles for regulatory best practice, good regulation minimises the exercise of bureaucratic discretion. In this case it must not be allowed to play a part in determining safety concern for existing products, and must be subject to rigorous independent scientific scrutiny.

While we do not support the introduction of such a re-registration scheme, should it be introduced there are certain areas where improvements could be made. The Draft Exposure Bill should ensure that registrants have recourse to independent scientific assessment of the APVMA decision, prior to the formal administrative appeal stage. Further, registrants should be given the opportunity to form task forces to pool resources should additional data be required to be generated. This is already a practice well established in Europe under the REACH programme so there should be no difficulties in mirroring similar type of processes in Australian law. Further, the Draft Exposure Bill should also contain a clause which requires the APVMA to Gazette at least six months prior to the expiry date the list of actives and products containing those active under consideration. A written notification 14 days prior to expiry is insufficient warning, particularly at the beginning of a new process.

In addition to our comments, Accord also strongly supports the views expressed by CropLife in its submission on Schedule 2.

Schedule 3 – Streamlining processes for giving and receiving information

Accord welcomes reforms that can be demonstrated to deliver efficiency reforms to the APVMA such as the introduction of electronic lodgement. Improving the APVMA's efficiency will permit it to better meet its statutory obligations to deliver regulatory decisions within the required time frames. However, care must be taken to ensure that the reforms proposed genuinely result in greater efficiency across the regulatory system as a whole. It would not be acceptable if the APVMA was only able to improve its administrative efficiency by increasing the regulatory burden placed upon applicants and registrants.

Accord fully supports the use of overseas hazard assessments in consideration of applications in the Australian context. All Australian regulatory agencies could benefit from adopting this approach. We do not see that hazard assessment data needs to be reassessed by Australian regulatory agencies. The risk assessment and risk management elements may require consideration, but not the intrinsic hazard of an entity. Assessing data which has already been assessed by comparable regulatory authorities with comparable health, safety and environmental outcomes is an inefficient use of limited resources. We refer you to the PC views on this at p217 and p218 of its report.

The Draft Exposure Bill could be strengthened to ensure that the APVMA gives appropriate consideration to the use of overseas data. Recently the New Zealand Government introduced the Natural Health Products Bill for the regulation of these products. While these products are recognised as low risk, nevertheless, the New Zealand Government recognises that efficiencies can also be gained through the adoption of equivalence. The Natural Health Products Bill contains a clause to declare recognised authorities which *"…it must satisfy itself that it administers a system for the regulation of natural health products that is equivalent to or more robust than the system administered under the Act.* The recognition of overseas data, certain assessments, monographs and/or regulatory decisions could be facilitated by the giving the APVMA the power to recognise as equivalent authorities and/or their decisions through an express condition in the Bill.

Accord is concerned about the lack of any cost benefit analysis for the reforms contained in the Draft Exposure Bill. As the reforms have potentially both significant risks and benefits to applicants, registrants and approval holders, it is critical to be assured that the reforms will deliver a net benefit to industry. Without this assessment, how can industry and policy makers be assured that the reforms will deliver the efficiencies and expected cost savings. Several of the reforms proposed, by implementing inflexible approaches to accepting new data or changing application categories, may in

fact be decreasing the overall efficiency of the regulatory system. Accord members are very concerned about the potentially overly rigid approaches being proposed, as some degree of flexibility allows for outcomes with which the APVMA and applicant can be satisfied.

Further, if the proposals operate in such a way that applications are refused due to minor technicalities, then the applicant is likely to resubmit that application. Members have advised that registrations have been held up because they submitted data in a graph on the basis of past experience when on this occasion, the assessor wanted it in table form. Such a hold up on this basis is clearly ridiculous, but it occurs and on the basis of the proposed administrative changes could lead to the application being rejected.

This could result in the APVMA having to process the application several times, and requires the applicant to pay multiple application fees. As application fees do not cover the full cost of conducting a risk assessment for the product, this process would not be efficient for either the applicant or the APVMA. Particular concerns have been raised with Item 12 which removes the possibility for an applicant to rectify defects in their application. Applicants may make minor errors and there should be provision for correction without the need to resubmit. Also, applicants may not always at fault. At preliminary assessment (Screening) the APVMA sometimes raises a defect with an applicant due to an APVMA oversight or error which is **NOT** an error by the applicant e.g. the APVMA may have missed a piece of required information, even though it is clearly stated in the application. The APVMA can also sometimes request information which is not required. Electronic forms and submissions should improve these anomalies but industry needs to be fully involved in this development.

A preferred system must incorporate some flexibility to enable the APVMA to properly assess inadvertenly 'defective' applications that can be readily remedied, while precluding assessment of those applications that are so poor and incomplete that they present an unacceptable drain on APVMA resources. A well designed electronic application system should help considerably with this.

Members have raised concerns as to what extent the APVMA will impose the proposed 'no amendments' approach. While members can understand that that the APVMA may not welcome new data which requires evaluation, it should still be acceptable to amend items such as product names or some label wording which do not require evaluation.

These issues again highlight the need for a comprehensive risk framework to be implemented prior to commencement of these arrangements. The risk framework must provide greater certainty to applicants about how their application will be assessed to facilitate better quality and more complete applications that can be rapidly assessed by the APVMA. Industry will also require much better guidance material. Currently some parts of MORAG are not sufficiently detailed to provide adequate guidance on the data needed for an application. This inadequacy in guidance information plus the prevention from making amendments would create a difficult environment for applicants.

Pre-application assistance is being proposed as a key initiative to overcome poor quality for some of the applications received. Accord does not believe that formalising and charging for pre-application assistance will achieve the expected outcome of improved applications, as it is doubtful that the applicants who submit poor applications are sufficiently engaged in the whole registration process to seek pre-application assistance. It would be the already engaged applicants who are more likely to use this. The current less formal approach to pre-application assistance is very valuable and Accord members have indicated they would not want to lose this flexibility. This is another example of a move to a more rigid approach associated with an increased cost burden on industry. We recommend that alternative options be considered to address this problem specifically targeted at those who over-use or abuse the system.

Items 14 to 19 remove the opportunity for applicants to rectify applications and for the APVMA to defer consideration of applications. This reform can only be accepted where it can be demonstrated that they will provide a net efficiency gain. Again, prior implementation of a comprehensive risk framework will be essential to give applicants the information that they need to develop and submit high quality applications. This raises similar concerns to those expressed above. Some amendments should be acceptable; it presumes that defects/deficiencies are always due to applicants whereas the APVMA itself can make errors in its assessment and applicants will need to have a simple, fast means of challenging these. There is potential for a lot of time to be wasted challenging an APVMA error and having it corrected.

Items 22 and 23 specify the information that the APVMA is required to consider when conducting chemical reviews. The intention is to facilitate the APVMA's capacity to complete chemical reviews in a timely manner and to encourage approval holders and registrants to submit any data at an early stage. However, an unintended consequence of this approach may be that the APVMA is required to approve an active constituent or product when it has new information that raises additional concerns about the risks associated with its use. These provisions preclude the APVMA from considering that information. The APVMA must always be allowed to consider all the data available to it to ensure that its assessment of chemicals is both accurate and meets contemporary standards. Allowing all information to be assessed will help preclude the possibility that the APVMA would approve an active constituent and then be required to immediately place it under review again. A process where this occurred would be neither efficient nor effective for either industry or the regulator.

Items 22 and 23 also note that fixed timeframes will be imposed for completion of chemical reviews. Regulations setting the fixed time for the review must be long enough to allow time for approval holders and registrants to negotiate and establish review task forces, generate necessary data (which may mean multiple growing seasons' field trials) as well as allowing the APVMA sufficient time to assess any data generated.

Item 32 requires the APVMA to decide applications within the total elapsed time established by the regulations. At this stage, the proposed timeframes are not available as supporting regulations have yet to be drafted, however, the timeframes that are ultimately specified must reflect the time that will be required to assess the most complex applications. Implementation of fixed timeframes, as noted elsewhere in this submission is predicated on improving the quality of applications made to the APVMA. Improving the quality of applications is in turn reliant upon a published comprehensive risk framework. Industry requires the ongoing flexibility of having the possibility of agreeing an extension to a timeframe with the APVMA. It is not clear whether this provision results in the preliminary assessment time being included in the overall application timeframe or not.

Accord would not support total elapsed timeframes for determining applications if it meant that the APVMA was required to refuse an application in circumstances where it was unable to complete an application within the required time frame. This would simply lead to another application being made and increase the administrative burden on the APVMA and the regulatory burden on the applicant.

Item 45 specifies when the amendments in Schedule 3 apply. As many of the proposed legislative reforms are reliant on the existence of a comprehensive risk framework, this item must be reviewed to ensure that it allows sufficient time for the risk framework to be developed.

Members attending the Stakeholder Forum noted the APVMA advice that they were working towards sending only one deficiency letter for an application. They would then make their decisions about the application based on the applicant's response. Accord does not support this concept as a single letter could only be sent at the end of evaluation, thus we could expect it to increase the overall timeframe compared with the current approach which allows matters in different modules to be dealt with as they arise during the evaluation. There are also concerns that it could result in a conservative approach

from the APVMA in the deficiencies raised and very limited opportunity to challenge the deficiencies, as the APVMA makes its decisions on the application based on the applicant's response to that single letter.

Schedule 4 – Enforcement

Accord supports reforms that are designed to give the APVMA an appropriate range of tools to enable it to effectively administer the Agvet Code and to also identify and respond to incidents of non-compliance. We note however, that model regulatory frameworks adopt a high level of regulatory intervention at either the pre or post market phase, not at both. The proposed amendments to increase the APVMA's suite of compliance tools increase its powers in regard to post market activities. We have seen no commensurate reduction in pre-market intervention. In addition to enhanced compliance powers there is a greater post-market burden in relation to the proposed re-registration scheme. An alternative to an expensive re-registration scheme is to improve post market monitoring of products though increased spot auditing and for the regulator to be seen to be active in the marketplace.

In implementing the new suite of powers it is essential that adequate training be provided to APVMA compliance officers and that adequate independent oversight and monitoring of their activities is routinely undertaken to ensure that powers are not misused. Industry will also require education and training to ensure they understand the full suite of reforms and a that suitable transition period for commencement of the new powers is provided.

In addition to our comments, Accord also strongly supports the views expressed by CropLife in its submission on Schedule 2.

Schedule 5 – Data protection

Accord supports the views expressed by CropLife in relation to Schedule 5. In addition, in an effort to reduce costs, the legislation should permit task forces to submit shared data and to be recognised as data owners as is done in the EU and USA.

Schedule 6 – Arrangements for Collecting Levy

Accord supports the most effective and efficient collection of the sales levy which may or may not be the APVMA. Only if it can be demonstrated that alternative collection arrangements will be more efficient than those currently in place, would we support this reform. However, we see no justification in the statement that moving the levy collection from the APVMA has anything to do with improved transparency or improving confidence in the APVMA.