Animal Health Alliance (Australia) Ltd
ABN: 76 116 948 344
Address: Level 2 AMP Building
1 Hobart Place
Canberra ACT 2601
Locked Bag 916
Phone: 02 6257 9022
Fax: 02 6257 9055
www.animalhealthalliance.org.au

17 December 2012

Committee Secretary
Senate Standing Committees on Rural and Regional Affairs and Transport
PO Box 6100
Parliament House
Canberra
ACT 2600
Australia

Email: ratt.sen@aph.gov.au

Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 – Animal Health Alliance (Australia) Ltd Submission

The Animal Health Alliance (Australia) Ltd (the Alliance) is the voice of the animal health industry in Australia. It represents registrants, manufacturers and formulators of animal health products. The association's member companies represent in excess of 85 per cent of all animal health product sales in Australia (ex factory gate). The Alliance manages both national and state issues with the objective of ensuring its members can operate within a viable regulatory environment. The Alliance also contributes to sustainable industry risk reduction practices that provide business opportunities to members and add value to the broader Australian community.

The Alliance welcomes the opportunity to offer a submission to the Senate Standing Committees inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012.

The new legislation underpins the future operation and efficiency of the national regulator of veterinary chemical products in Australia – the Australian Pesticides and Veterinary Medicines Authority (APVMA).

The APVMA is the primary regulator that the Alliance member companies have to engage with to obtain product registration along with label and active constituent approvals before their products can be legally sold in Australia.

The Alliance has been actively engaged with APVMA, Department of Agriculture, Fisheries and Forestry (DAFF) along with Federal and State governments since 2006 seeking fundamental changes to the APVMA, regulations plus operational guidances and processes so to overcome inherent inefficiencies in delivery of services to the animal health industry in Australia.

Please find attached a copy of a suite of submissions supplied by the Alliance over the recent years highlighting the inherent problem with APVMA and offering solutions.

This latest attempt by government to deal with APVMA inefficiencies through the Agricultural and Veterinary Chemicals Legislation Amendments Bill 2012, does not, in the Alliance's opinion, do anything to address the fundamental problem. In fact this new Bill actually increases the regulatory burden on industry and imposes more work for the APVMA without any demonstratable cost/risk benefit to warrant such a move.

The new Bill adds over 200 new pages of legislation for APVMA to administer and it removes none from the existing legislation. An additional cost of approximately AUS $8 million is likely to be imposed on the agvet chemical industry to implement this Bill in its first year of operation.

The Alliance finds it extremely frustrating that the present Federal Government espouses its platform of reducing regulatory compliance costs on businesses and then tables this Bill.

The Alliance and its member companies are not averse to good regulation and are prepared to pay for an efficient and effective regulatory system. This present Bill however has not demonstrated a market failure with the present regulation of veterinary chemical products that warrant this new legislation. In addition, this proposed new Bill has not been presented from a cost/risk benefit basis. In fact, the Exposure Draft preceding this draft Bill offered no examples from overseas regulators where similar proposed regulatory changes as those in the draft Bill, have been implemented and are needed for veterinary chemical product regulation. All the evidence offered in the Exposure Draft relates specifically to agricultural (crop) chemical products.

The Alliance has been active over the last years in attempting to highlight to Government and DAFF, while drafting the new Bill, the flaws and impediments in the proposed new processes intended to operate to deliver this new Bill. The Alliance has issued a series of media releases in an attempt to highlight the problem and also solutions. (See attachments).

Yours sincerely

Dr Peter Holdsworth AM FAICD
Chief Executive Officer

Animal Health Alliance (Australia) Ltd

ATTACHMENTS:

Submission:

Attachement 1: *17 December 2010 – Better Regulation of Agricultural and Veterinary Chemicals – Policy Discussion Paper.*

Attachments 2: *8 April 2011 – Consultation Regulation Impact Statement – A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals.*

Attachment 3: *28 February 2012 – Alliance response to the APVMA Cost Recovery Discussion Paper.*

Attachment 4: *29 February 2012 – Alliance submission to the Better Regulation of Agricultural and Veterinary Chemicals Regulation Impact Statement.*

Attachment 5: *20 October 2012 – Agricultural and Veterinary Chemicals Legislation Amendments Bill 2012 Revised Exposure Draft September 2012 – Animal Health Alliance (Australia) Limited Submission*

Media Releases:

Attachment 6: *March 2012 - Delivering reforms that make a difference and achieve the better regulation of agricultural and veterinary chemicals.*

Attachment 7: *March 2012 - Delivering reforms that make a difference and achieve the better regulation of agricultural and veterinary chemicals – Impact on Farmers.*

Attachment 8: *8 August 2012 – Handicapping Australian Farmers.*

Attachment 9: *26 September 2012 – Pet health worry on the horizon.*

Attachment 10: *10 December 2012 – Red tape threatening animal health.*

SUBMISSION - ATTACHMENT 1.

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ABN: 76 116 948 344
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1 Hobart Place
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Phone: 02 6257 9022
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www.animalhealthalliance.org.au

17 December 2010

Agvet Chemicals Early Harvest and APVMA Reforms Team
Agricultural Productivity Division
Department of Agriculture, Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601

Better Regulation of Agricultural and Veterinary Chemicals **- Policy Discussion Paper**

The Animal Health Alliance (Australia) Ltd (the Alliance) is the voice of the animal health industry in Australia. It represents registrants, manufacturers and formulators of animal health products. The association's member companies represent in excess of 85 per cent of all animal health product sales in Australia (ex factory gate). The Alliance manages both national and state issues with the objective of ensuring its members can operate within a viable regulatory environment. The Alliance also contributes to sustainable industry risk reduction practices that provide business opportunities to members and add value to the broader Australian community.

The Alliance appreciates the opportunity to provide input into developing reforms to ensure better regulation of agricultural and veterinary chemicals.

If you have any queries on our submission please do not hesitate to contact me.

Yours sincerely

Dr Peter Holdsworth AM FAICD
Chief Executive Officer
Animal Health Alliance (Australia) Ltd

ATTACHED: Animal Health Alliance (Australia) Ltd Submission to:
Better Regulation of Agricultural and Veterinary Chemicals - Policy Discussion Paper

SOLUTIONS FOR THE FUTURE

Animal Health Alliance

Animal Health Alliance (Australia) Ltd

Submission to

Better Regulation of Agricultural and Veterinary Chemicals
Policy Discussion Paper

17 December 2010

Locked Bag 916
CANBERRA ACT 2601

www.animalhealthalliance.org.au

Phone: +61 2 6257 9022 | Fax: +61 2 6257 9055

Contents

EXECUTIVE SUMMARY

Government's recognition that "the system (APVMA and NRS) is not working as effectively as it should ….." is the first key step to amending the current regulatory system for agvet chemicals in Australia. The Alliance commends government for taking this first step.

Australia, along with New Zealand, is unique within the OECD in having a single regulator in each country for both agricultural and veterinary chemicals. When reforming such a regulator it is pertinent to ensure that a "one size fits all" approach is not the starting point for considering eventual reform outcomes.

All reforms being considered must be challenged in the first instance through a "cost benefit" analysis – where is the market failure, what needs to be reformed, what are the options to be considered, what are the costs involved compared to the potential impact of the deliverables, who pays, how and when and what are the likely unintended impacts of the reforms?

Initiatives to improve the transparency and efficiency of product assessments and determinations, be it via development of risk frameworks, clearer definitions of low risk products or the expedited assessment processes, on a fee for service basis, are seen as positive steps in the reform agenda.

Greater use by APVMA of overseas assessment reports originating from like regulators on the same product are similarly seen in a positive light. The Alliance however, only sees this initiative as the first step towards the bigger goal of moving to mutual recognition of assessments and decisions by like regulators dealing with the same product. An obstacle at present to achieving this goal is Australia's unique requirements, among OECD regulators, for product applicants to supply APVMA with local efficacy and trade dossiers to support various product applications. Recognition in this policy position paper of the potential to satisfy APVMA on efficacy and/or trade for low risk products in ways other than with traditional data dossiers is seen as highlighting the challenge with these unique data requirements.

The Alliance has not sighted in this policy discussion paper any demonstrated evidence of market failure with veterinary chemical products compliance programs that would support the argument for a tiered reapplication, review and re-registration scheme. As such, the Alliance cannot support this proposed scheme.

Proposals for an independent science panel and expert advice services linked to the removal of the existing Advisory Board are considered in a positive light.

Challenges with APVMA legal and compliance activities are recognised, but the Alliance believes they need to be considered as part of the COAG review of the NRS before any reforms are decided on.

INTRODUCTION

The Alliance has consistently stated in submissions over the last 5 years that to improve the workings and operation of the APVMA specifically and of the National Registration Scheme (NRS) more broadly, we first need to acknowledge the failings of the present regulatory system. In this context the Alliance welcomes Minister Ludwig's statement in the "Foreword" of this policy discussion paper that "… the system is not working as effectively as it should …". Furthermore we commend the Minister for his proposal here to amend the current system to promote better regulation of agvet chemicals.

The APVMA, along with the New Zealand regulatory system, appears to be unique within OECD countries with each country establishing a single regulator controlling agvet chemicals. While it appears not to be the intent within the present policy discussion paper to discuss the prudence of such a move, it is pertinent to ensure in this present exercise that a "one size fits all" approach for both agricultural and veterinary chemicals does not drive the eventual reform outcomes.

An acute focus for the Alliance in any proposed reforms is what is the "cost benefit" to the Australian community from proposed reforms? The APVMA is a science based, independent Federal regulator that works on an activity based costing model and is funded nearly 100% from fees and levies imposed on the industries it regulates on a "user pays" principle. Any proposed reforms that result in additional resources being required by APVMA need to be assessed carefully for their overall "cost benefit" to the Australian community. Additional resources required by APVMA under such a funding model invariably mean fees and levies will be adjusted to reflect the increased costs for the regulator to undertake business. This impact needs to be assessed and managed very carefully to minimize any negative market fallout. Australian farmers in particular are "price takers" not "price setters" in the global commodity food market. Increased regulatory costs of market entry to supply veterinary chemicals in Australia cannot automatically be argued as a cost that can be passed on to the end user of chemical products.

In this focus on "cost benefit" of regulatory activities the Alliance reconfirms its opposition to APVMA managing trade risk as a condition for registering veterinary chemical products and specifically approving product labels. In previous submissions to government we have detailed our concerns on how Australia appears to be out of step with other OECD regulators in imposing this obligation on veterinary chemical registrants. Similarly, in a contemporary regulatory world it is opportune within this reform framework to consider the "cost benefit" of the ongoing, almost routine requirement for various product applicants to generate comprehensive local efficacy and safety data and the conservative risk profile taken by APVMA in assessing efficacy data.

The Alliance recognises the "one off" financial contribution to the APVMA that the Federal government has committed to supply over a 4 year period. We note that this $8.75 million dollars is particularly focused on the need for a contemporary information technology system within the regulator with the residual funds needed to ensure the APVMA's financial viability until an amended cost recovery model is adopted and implemented. The Alliance commends the Federal government for allocating these financial resources at this time however we understand the future intent is to recoup a component of this money from the regulated industry. We are on the record as stating that our industry strongly believes that there are components of the APVMA operation that are not activities that should be financially recovered directly from the regulated industry. An information technology backbone falls into this category. We further believe that the compliance activities and "non core business activities "of APVMA should be funded directly by government as "public good" functions.

The proposed Commonwealth reforms to legislation and regulations articulated in this policy discussion paper are addressed in this Alliance submission. In addition, we offer some additional points for

consideration in the overall context of reforms. The Alliance notes that this policy discussion paper is a separate initiative to the yet to be released options paper/regulatory impact statement to emerge out of the COAG review of the NRS. We reserve the right to revisit our comments and position offered here subject to the content of the yet to be released position/options paper on the COAG review of the NRS becoming public.

RATIONALE FOR THE APVMA EXISTING

The Alliance strongly believes that a basic omission in the "preamble" of the APVMA legislation, which sets the rationale for the regulator being established, is the positive benefits to the Australian community of having access to appropriately regulated agvet chemical products. We believe the aims of APVMA should include ensuring Australian primary producers, performance animal owners and pet owners have access to the latest innovative technology. In this context we recommend that the APVMA "preamble" be amended to include wording to the effect that "… the APVMA activities include facilitating the expeditious availability of agvet chemical solutions to Australian crop, livestock, performance animal and pet owners so to offer a positive economical and social benefit to the Australian community".

1. IMPLEMENTING COMPLETE RISK FRAMEWORKS FOR AGVET CHEMICALS ASSESSMENT AND REVIEW

The Alliance fully supports this initiative. We note that this activity is well overdue and is a recurring recommendation from various government reviews of the APVMA over many a year. Any APVMA risk frameworks need as a starting basis to recognise that "one size will not fit all" and as a minimum separate risk frameworks will be required for agricultural chemicals to those developed for veterinary chemicals.

The Alliance notes that at present the policy discussion paper indicates that the risk frameworks will be developed by APVMA and its co-regulatory partner agencies. The policy discussion paper, while specifically stating which government agencies will work with APVMA to develop overarching risk frameworks, does not offer specifics on who will initially work with APVMA in developing chemistry and manufacture; residues and trade; efficacy and safety components. The role and position of AQIS as a partner agency to APVMA needs to be addressed in this initiative. AQIS, like other co-regulatory partner agencies, should deliver a service for APVMA for biological products according to defined timeframes and against transparent policies/guidelines. The role for other (non government) APVMA stakeholders in this process is silent. Our industry, as a key stakeholder in the future viability and success of APVMA, is eager to offer our resources domestically and if needed internationally, to ensure that the final risk frameworks are contemporary.

Initiatives proposed further on in the policy discussion paper, specifically in relation to alternative ways that product applicants may in the future be able to satisfy APVMA in relation to efficacy and/or trade, reinforce the importance for these risk frameworks for future reforms in the regulators operation.

It is imperative that resources required within APVMA and with the government agencies to develop these risk frameworks do not compromise the delivery of core APVMA business in assessing and registering veterinary chemical products plus approving labels.

2. IMPROVE THE QUALITY AND EFFICIENCY OF AGVET CHEMICAL ASSESSMENT AND REGISTRATION PROCESS

2.1 Lodging applications

The Alliance supports the intent of the initiative to offer pre-application submission assistance to applicants if required. Such a service should not be mandated as many multinational veterinary chemical companies employ contemporary regulatory affairs teams within their organisations and would prefer the flexibility of deciding on a case by case basis whether to avail themselves of such a service.

As the APVMA is a cost recovery regulator and implements this as a "user pay" principle it is not clear at this time how the regulator would ensure that the internal costs involved in delivering such a service were recouped equitably. If an applicant does not need to use and pay for this service up front and if the APVMA is to rely on recouping this cost via fees on applications submitted, then how will equity be ensured with respect to applicants who don't avail themselves of such a service? Is the intent that application fees be adjusted to reflect this up front advice? If so will applicants who do not use such a service still have to pay the same application fee as those applicants who do use the service? Alternatively, if the intent is to "absorb" this upfront cost and recoup it via the sales levy, then we face the perennial problem of cross subsidisation between applications. Further detail is required on how this actual process is intended to operate and have costs recouped. The Alliance would not support a process that relied on the sales levy as the mechanism to recoup this cost to APVMA. Cross subsidisation in cost recovery at any level is not supported by our industry and has been contrary to Federal government policy.

The initiative here is likely to be more attractive to smaller or minimally resourced veterinary chemical companies. As such there may be value for APVMA in considering this initiative to liaise with other Federal government departments that offer assistance (grants) to small business to assist them in dealing with regulatory imposts in doing business.

2.2 Assessing applications

The Alliance in principle supports the intent of this initiative. While the intent here is to focus just on low risk products, the fundamental issue of APVMA repeating assessments of efficacy and safety data on a product that may have already had that data comprehensively assessed by a similar OECD regulator is an area that needs further assessment in this reform process. Similarly the fundamental basis for APVMA regulating trade risk (and by inference Export Slaughter Intervals [ESIs]) needs a comprehensive review. As a starting point government needs to appreciate how other country regulators, such as New Zealand, manage trade without requiring ESIs as the basis of risk management. In addition, from a "cost benefit basis" government needs to assess how other OECD countries manage regulation of veterinary chemical products without regulating trade within their remit. Until these ongoing efficacy and trade issues are fully analysed and a "real" risk appetite is developed and communicated it is somewhat problematic in moving forward on this reform to decide what could be low risk products.

2.3 Assessment timeframes

The Alliance supports this proposal under the conditions expressed within the policy discussion paper. An accelerated assessment process being offered on fee for services basis and not compromising the existing assessment process and service to product applicants has merit. It is imperative under such a model that the existing assessment system is not compromised as the credibility of APVMA with its independence and impartiality, must remain paramount. Similarly if such a system is to be offered in the future it will be essential that this service is available if and when required by industry. Availability of the required technical expertise will be an ongoing challenge in operating both systems as human resources with required expertise is always problematic.

If such an accelerated assessment process is implemented, it could be complementary to APVMA recognising assessments of decisions already made by like overseas OECD regulators on the same products.

3. ENHANCING THE AGVET REVIEW ARRANGEMENTS

The Alliance seeks further clarity on the reform being proposed here. At present the APVMA operates a chemical review program that is generally recognised as wanting. The proposal to initiate a tiered and targeted reapplication, review and re-registration scheme in addition to the existing review program is potentially confusing. Is the intent that over time the new proposal will supersede the existing chemical review program? No indication is given in the policy discussion paper of the "cost benefit" of the new proposal. The new proposal, as described, would be resource intensive for both industry and the regulator. Invariably regulatory costs for running such a scheme would be passed on to the regulated industry. No "market failure" argument has been presented in the policy discussion paper to justify considering such a scheme for veterinary chemical products. While it is recognised that community group pressure may warrant such a scheme being proposed, the fundamental question still stands of where is the "market failure" to justify such a scheme?

Regulation of veterinary chemical products in Australia encompasses a comprehensive manufacturing licensing scheme (MLS) as well as a well established adverse experiences reporting scheme (AERP vet). As mentioned earlier in this submission, it is imperative that any reforms adopted do not automatically focus on "one size fits all" for agvet chemical products.

The proposed targeted reapplication, review and re-registration scheme would be working in a commercial environment where the Australian market is dominated by generic agvet chemical products. The incentive for such registrants to allocate resources, let alone generate contemporary data for their existing products is problematic. For multinational registrants of innovative products in a generic dominated commercial environment, the need for credible and comprehensive data protection compensation would be paramount to underpin any defensive R & D required under such a proposed scheme.

With the existing regulatory MLS and AERP (vet) operating, what is the justification for arguing for this additional level of regulatory impost on the veterinary chemical industry? No credible argument is presented in the policy discussion paper to indicate that the existing veterinary chemical products compliance programs are wanting.

At present the APVMA operates on an annual budget of around $24 million and nearly all of this is recouped via fees, charges and levies from the regulated industry. This figure equates to close to a 1.2% cost of annual sales of agvet chemicals in Australia at ex factory gate (veterinary chemical sales $800 million; agricultural chemical sales $1.3 billion). This 1.2% figure is at the extreme top end when compared to like regulatory cost recovery figures in other OECD countries. In fact in Germany the regulatory cost recovery figure is 1.2% of veterinary chemical sales and this percent figure is double the regulatory cost recovery from the human pharmaceutical industry in Germany. This disparity is now the basis of a push for a review of the regulatory cost on the animal health industry in Germany Animal Farm Article As the APVMA cost recovery, in delivering its present services, is at around 1.2% of industry sales, any new regulatory initiatives will increase that percentage further. The need for a reapplication, review and re-registration scheme for veterinary chemical products has not been demonstrated from a "cost benefit" let alone a "risk benefit" basis in this policy discussion paper and as such the Alliance cannot support this proposal.

4. USING OVERSEAS ASSESSMENTS TO THEIR FULL EXTENT

The Alliance is on the record as stating that we believe APVMA, with a clearly developed risk framework and risk appetite, should be able to entertain recognising and accepting assessments and more importantly the regulatory decision made by like OECD regulators on the same product they are assessing at a particular time. This statement obviously assumes that the product at issue is the same, with the same use pattern, claims and originating from the same manufacturing plant etc. The proposal in this policy discussion paper if implemented could be a first step in moving to the ultimate goal. In moving to this goal APVMA/DAFF would need to obtain commitment from other government agencies that provide product assessment advice to APVMA.

The reference in the policy discussion paper to the Stockholm and the Rotterdam Conventions is of concern to the Alliance. While not impacting directly at this point in time on veterinary chemicals the position advocated here to formally recognise the processes for Persistent Organic Pollutants and Prior Informed Consent in the agvet legislation is a new initiative that needs further clarification and justification.

5. ESTABLISHING AN INDEPENDENT SCIENCE PANEL

The Alliance would see the establishment of such a panel as a positive move if it occurs in parallel with the disbanding of the existing APVMA Advisory Board. The Alliance has seen the existing Advisory Board as being problematic for some time with its ability to offer APVMA contemporary advice as being challenging. The example given in the policy discussion paper of the scientific panel reporting annually on the APVMA's progress with reducing the backlog of reviews and improving the efficiency of assessments is problematic to us. The Alliance does not see this example as an appropriate role for science based experts. If this role is the intent for such a panel we would then suggest that the panel title be amended to something like "independent audit panel".

6. ENHANCING THE PROVISION OF EXPERT ADVICE

The Alliance can support this proposal in principle. We do however, note that nowhere is it stated that the intent of this advice to be objective. Considering that these advisors would be appointed by the APVMA Chief Executive Officer, the Alliance believes that concerns may be raised on the transparency and objectiveness of this activity unless appropriate reporting and transparency commitments are given. The question of whether this advice is linked to core business activities or "public good" roles needs to be discussed further in respect of how this activity will be funded. This proposal, if implemented, will offer the opportunity for the continued roles of the Community Consultative Committee and the Industry Liaison Committee to be reassessed.

7. IMPROVING LEGAL INTERACTION WITH THE APVMA

The Alliance has been monitoring for some time the ongoing problematic issues APVMA face in delivering a viable and credible compliance role within certain sectors of our industry. The case example given in the policy discussion paper is a sobering example of disconnect between legislative intent and the court's interpretation. Perhaps further consideration needs to be given by government to the better recognition of industry stewardship programs as a mechanism of self regulation within industry.

8. IMPROVING THE APVMA'S COMPLIANCE ENFORCEMENT CAPACITY

The Alliance is on record with earlier submissions to government in pushing for a regulator separate to APVMA to prosecute the activities of compliance and control of use. Our position on this issue has not shifted. As such we reserve our comments on this point and await the release of the consultation paper relating to the COAG review of agvet chemical control of use.

SUBMISSION - ATTACHMENT 2.

Animal Health Alliance (Australia) Ltd
ABN: 76 116 948 344
Address: Level 2 AMP Building
1 Hobart Place
Canberra ACT 2601
Locked Bag 916
Phone: 02 6257 9022
Fax: 02 6257 9055
www.animalhealthalliance.org.au

8 April 2011

PSIC Secretariat
Agricultural Productivity Division
Department of Agriculture, Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601

Consultation Regulation Impact Statement –
A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals

The Animal Health Alliance (Australia) Ltd (the Alliance) is the voice of the animal health industry in Australia. It represents registrants, manufacturers and formulators of animal health products. The association's member companies represent in excess of 85 per cent of all animal health product sales in Australia (ex factory gate). The Alliance manages both national and state issues with the objective of ensuring its members can operate within a viable regulatory environment. The Alliance also contributes to sustainable industry risk reduction practices that provide business opportunities to members and add value to the broader Australian community.

The Alliance appreciates the opportunity to provide input into the *Consultation Regulation Impact Statement – A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals.*

The Alliance supports initiatives to make veterinary chemical product regulation more effective and efficient in Australia. The Alliance has been on the record for many years in submissions to government observing that the processes underpinning assessment and registration of veterinary chemical products and approval of labels could be significantly improved to facilitate and encourage greater innovation in Australia.

The varying compliance approaches and differing regulations used in Australian jurisdictions in relation to control of use have the potential to unnecessarily increase the risks associated with veterinary chemical product use. Differences in state/territories regulation with respect to permitted product uses, user/advisor training and accreditation, in addition to restrictions on particular veterinary chemical products available in certain locations, adds unnecessary compliance costs and confusion on the industry.

The Alliance supports in principle the proposals to nationally harmonise rules and regulations regarding the assessment, registration and control of use of veterinary chemical products. Similarly, the Alliance commits to working with the government to ensure that the best outcomes for the veterinary chemicals industry, farmers, consumers and the community can be achieved. This is likely to include a mixture of regulatory and stewardship outcomes that can deliver effective compliance at minimal cost to the Australian community and economy.

The Alliance comments supplied in this submission only address the relevant sections of this Consultation Regulation Impact Statement (RIS) that are new and that the Alliance has not already addressed through its earlier submissions to government (attached separately), namely:

- Animal Health Alliance submission to the discussion paper on "*A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals*" - 9 February 2010; and

- Animal Health Alliance submission to the "*Better Regulation of Agricultural and Veterinary Chemicals Policy Discussion Paper*" - 17 December 2010.

Yours sincerely

Dr Peter Holdsworth AM FAICD
Chief Executive Officer
Animal Health Alliance (Australia) Ltd

SOLUTIONS FOR THE FUTURE

Animal Health Alliance

Animal Health Alliance (Australia) Ltd

Submission to

Consultation Regulation Impact Statement – A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals

8 April 2011

www.animalhealthalliance.org.au

Phone: +61 2 6257 9022 | Fax: +61 2 6257 9055

EXECUTIVE SUMMARY

The Alliance supports the development of a new effective and efficient regulatory scheme. An effective and efficient regulatory system must seek to analyse the risk/benefit associated with the responsible veterinary chemical product use, versus the costs that may occur when these products are inappropriately used.

To deliver the new efficient and effective regulatory system, the Alliance considers the following points as pivotal.

- The new scheme must be a cost effective user pay system with respect to registration;
- Separation of regulation and control of use;
- Harmonisation of control of use legislation across Australia;
- Establishment and consistent application of a transparent risk management approach; and
- The need for an effective post-approval product review process.

The Alliance, along with CropLife Australia, has an established record of addressing environmental and regulatory risks through stewardship. Our ***drum****MUSTER,* ChemClear® and Accreditation and Training programs assist in the sustainable life cycle management of veterinary chemical products. Many of the options for further national regulation could be met through self-regulatory or co-regulatory measures implemented and operated by industry in liaison with government. The Alliance believes that some proposed measures, such as training for users and advisors, could easily be implemented at minimal cost through adjustments to existing stewardship schemes. These could realistically be modified, if needed, from the present purely private (industry) initiative to a government/private partnership.

The Alliance is particularly concerned by a lack of information regarding the comparative costs and benefits of potential options offered in this RIS. While the Alliance can assist with providing some information on the costs of alternatives, it is not possible to provide our members' definitive position about preferred options without a full consideration of their respective benefits and potential costs.

The Alliance believes there needs to be extensive ongoing consultation throughout the development of the new National Scheme.

5. GOVERNANCE OPTIONS

The Alliance continues to advocate our position as tabled in our earlier submission (Animal Health Alliance submission to the discussion paper on "*A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals*" - 9 February 2010) that there needs to be a separation between the pre-market risk assessment functions currently conducted by the APVMA, and the post-market compliance and enforcement functions currently performed by state and territory government agencies. Such an approach recognises the fundamental differences that occur between the pre- and post-market regulatory functions.

The APVMA conducts a rigorous, science based risk assessment of veterinary chemical products, their accompanying actives, associated product labelling and product manufacturing process prior to permitting the product be supplied. This process requires certain APVMA staff to posses the scientific knowledge, training and expertise to examine technical data and undertake assessments relating to the risk associated with the responsible use of products.

In contrast, the post-market control of use function necessitates a different set of tools and people skills. Rather than a scientific assessment, state and territory regulators currently employ a range of administrative, regulatory, educational and compliance tools to promote the responsible use of veterinary chemical products. This does not necessarily involve upfront scientific assessment, but rather a flexible and pragmatic approach to ensure that the correct tools are available and applied in circumstances to ensure the best outcome for users, animal welfare, consumers, the environment and trade. It will involve a mix of tools that might include communication and engagement strategies, community education programs, training and accreditation programs for chemical users and agronomists, as well as enforcement actions and prosecution for wilful or negligent misuse of veterinary chemical products.

Three options are presented in the RIS. These are:

1. *Maintain the APVMA's current assessment and registration role, with the Commonwealth, states and territories as partners overseeing the APVMA's policy and operational direction, but with delivery of other regulatory functions as deemed appropriate – at least those regarding training, licensing and accreditation – through a national agency, which is governed in partnership between the Commonwealth, states and territories. All other aspects of control of use would be managed by states and territories under harmonised regulations.*

The Alliance considers that the delivery of appropriate functions nationally, such as training, licensing and accreditation is likely to offer benefits to industry through:

- Improving the portability of competencies, skill sets and accreditations between jurisdictions. Product users who obtain the necessary competencies and accreditations would not be limited by jurisdictional boundaries, increasing competition for services;
- Ensuring that veterinary chemical product users are subject to one clear national standard. Irrespective of the jurisdiction that product users find themselves in, they would have greater clarity regarding their obligations when using veterinary chemical products; and
- Minimising risks to product users, animals, consumers, environment and trade by ensuring that all veterinary chemical product users have obtained a level of competency appropriate to the risks that they will be expected to manage when using veterinary chemical products. This level of competency may vary depending on the risks involved. Similar risks in different jurisdictions would therefore require similar competencies to be obtained and demonstrated.

This area is one where there is potential for cooperation between Governments and industry. Industry stewardship schemes such as Agsafe's Accreditation and Training Scheme already assist regulators to ensure that distribution and retail centres for agvet chemical products are meeting their legislative requirements under

Occupational Health and Safety, Dangerous Goods and Major Hazard Facility legislation. Similar arrangements should be explored before simply resorting to legislative solutions.

2. *Establish national bodies – one with responsibility for assessment and registration and another with responsibility for control of use of agvet chemical products.*

The Alliance supports this option, noting that it is broadly consistent with our proposal presented in our February 2010 submission to the Product Safety and Integrity Committee (PSIC), (Animal Heath Alliance submission to the discussion paper on "*A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals*" - 9 February 2010). This option is supported on the basis that:

- It is likely to deliver the greatest level of consistency of veterinary chemical product control of use regulation. It will prevent the "regulatory drift" that inevitably occurs between jurisdictions as they seek to take account of their own local circumstances, or interpret agreed rules in novel and unanticipated ways; and
- It potentially offers greater flexibility and efficiency in resource allocation as resources can be directed to those areas and regions where compliance and enforcement effort is more appropriate.

In recognition that states and territories have existing resources that could be deployed to deliver control of use services, these resources could be redeployed to provide control of use services for a national authority (not APVMA). This will ensure that users are provided with appropriate advice from a national authority presence within their region. The approach could be provided in much the same way as the current state-based control of use functions, where compliance officers are out-posted to regional areas from one central coordinating government agency. The use of these existing state control of use resources would ensure a smooth transition to the new control of use structure and avoid unnecessary additional resources.

Since control of use is clearly a 'public good' function, the cost of the new control of use structure is most appropriately borne by government. It would not be appropriate for registrants to contribute to funding control of use and this added cost would be a significant disincentive to registration and to bringing competitive and innovative products to the market.

3. *Maintain the APVMA's current assessment and registration role, with the Commonwealth, states and territories as partners overseeing the APVMA's policy and operational direction. Delivery of other regulatory functions, including training, licensing and control of use would be managed by states and territories under harmonised regulations.*

This option is not supported as, over time, any harmonisation of regulation is likely to be lost, and any benefits that may be accrued will quickly become lost as companies are again forced to comply with differing sets of regulation.

6.1 Assessment and Registration

The Alliance notes that many of the options proposed in this section reflect policy proposals contained in Minister Ludwig's Policy Discussion Paper: *Better Regulation of Agricultural and Veterinary Chemicals*. As the Alliance has already prepared its response to those proposals, they will not be reiterated in this submission. Rather, this Alliance submission will focus on those areas where clear proposals have been made that have not been addressed in the Alliance's December 2010 submission (Animal Health Alliance submission to the "*Better Regulation of Agricultural and Veterinary Chemicals Policy Discussion Paper*" - 17 December 2010), or where additional opinion from the Alliance membership may prove beneficial to the ongoing policy development process.

6.1.2 Efficiency in assessment and registration

Concerning the use of overseas data, the recent experience of registrants is that APVMA's external agencies are not prepared to adopt or seriously consider assessments already conducted by major overseas regulatory agencies. Overseas assessments should be considered and adopted, where appropriate, in the new regulatory system.

6.1.3 Assessment and use information

The Alliance supports veterinary chemical product users being given timely, up to date, and relevant information that is critical to facilitate the safe use of a product. However, the Alliance and its members are cognisant of the limitations of current labelling arrangements. New technologies may provide new solutions to ensuring that product users have access to the latest information for the product use.

While new technologies may be useful for obtaining the latest information, it cannot replace the requirement that up to date, relevant and reliable information be included on labels to ensure that adequate instructions are provided for users to be able to use and handle a product safely and appropriately. Not all product users have access to, or desire to use, modern information communication technology systems. For these individuals, the physically attached product label will be of prime importance.

Three options to address these issues are proposed in the RIS:

1. *Develop a common approach to product efficacy across jurisdictions to limit label complexity and label approval effort.*

The Alliance supports measures that would see a consistent approach to product efficacy across jurisdictions. Any measures that reduce and minimise label complexity are likely to result in better use outcomes.

2. *Require that companies put all their market labels on a single, web-based database.*

Placing labels on websites represents an opportunity for users to have access to the latest information on safe use of a chemical product. It also presents an opportunity for registrants to develop more targeted guidance information on how to use these products safely in specific circumstances without over-complicating labels or including excessive information that may not be relevant to that particular user.

Under this approach attached labels would be most restrictive, with online guidance providing information about risk management options that can be employed to allow greater flexibility in product application.

The Alliance does note that some governments and organisations (such as Infopest) have independently developed publicly accessible tools that contain many agvet chemical product labels. The Alliance believes a database containing all marketed veterinary chemical products should be available and this database should be delivered for use through a competitive tender process.

3. *Make no changes beyond those directly required by the Agricultural and Veterinary Chemicals Code Amendment Act 2010.*

Limiting changes to only those that are required under the Agricultural and Veterinary Chemical Code Amendment Act 2010 will not provide significantly greater benefit over and above that which is already in place. The Alliance would seek greater reform to create greater benefits for product users than would be provided if this option only were adopted.

While the Alliance has no specific costing data in relation to labelling amendments relating to veterinary chemical products, we note that CropLife Australia has recently examined the costs of redesigning labels to take into account new workplace chemical labelling requirements. CropLife Australia's costs of designing, printing and applying new labels, along with the cost of training users on how to interpret new label directions

and instructions was estimated to exceed $100 million. Very clear benefits to exceed these significant costs would need to be demonstrated before proposals to make changes to printed labels could be entertained.

6.1.4 Facilitating registration of low risk products

All APVMA registered products, when used in accordance with approved label directions represent an acceptable risk for users, animals, consumers and the environment. While the Alliance supports efforts to facilitate the registration of low risk products, care needs to be taken to identify those products that are genuinely low risk. In the existing APVMA risk analysis process with respect to veterinary chemical products, the level of risk is determined once the risk assessment has been conducted. Without that assessment, it is often not possible to determine the actual level of risk.

The Alliance notes that the proposal seeks to develop a reduced risk/low risk program that would have two elements. These are to:

- Encourage the substitution of lower risk, but conventional, products for existing registered products; and
- Facilitate registration of products that could be classified as 'low risk' products.

The APVMA, irrespective of the product being assessed, must be satisfied that a product does not present an unacceptable risk to human health, animals, environment and trade. The Alliance could not support a scheme that prioritised the assessment of 'low risk' product applications at the expense of conventional products.

Substitution of lower risk products for higher risk products may be an ideal objective, but it may have significant perverse outcomes. Unlike other areas of chemical regulation, farmers require a comprehensive tool kit of veterinary chemical products to manage pests, diseases and physiological ailments of animals. Resistance management strategies for example require the use of different veterinary chemical classes of products over time to manage animal welfare and productivity issues. This does require periodically using classes of chemical in veterinary chemical products that may be classified as 'higher risk'.

Substitution should not be used as justification to remove product label uses or cancel the registration of products. Ultimately, the substitution principle seeks to prioritise chemicals and related products on the basis of their hazard, rather than their risk. Following the risk assessment process conducted by the APVMA, when used in accordance with established label directions, all registered products can be considered to be of acceptable (low) risk. If a product presented an unacceptable risk to human health or the environment it would not be registered by the APVMA. Introduction of an additional hazard element to the risk assessment process will undermine the integrity of Australia's risk assessment approach to veterinary chemical product regulation. It may also undermine the credibility of the APVMA as a chemical product risk regulator.

For example, products that are approved as 'low risk' on the basis of a very low intrinsic hazard might not be as effective as established products but could still meet regulatory hurdles for registration approval. This could lead to a more significant and rapid development of resistant pests and microorganisms. A rapid loss of efficacy would undermine the APVMA's credibility as a regulator. In the absence of product substitution, resistance management strategies would largely control this risk through the use of a wide variety of chemical product tools, all of which could be considered low risk following APVMA assessment and product registration.

While the Alliance has not considered the likely costs and benefits of this proposal, we consider that there are likely to be significant costs associated with introduction of a substitution program that would not be outweighed through any reduction in risk.

Implementation of such a proposed scheme would also likely require the APVMA to undertake a massive education program. Up until now the public assumption has been that if APVMA registers a veterinary chemical product then the risk(s) associated with the legitimate use of that product were acceptable for a reasonable person to deal with. Under this new proposal the APVMA would need to educate the public that it is changing the way it will assess risk in the future for new products and presumable existing products when re-registered (if that process is implemented) or formerly reviewed. Alternatively the APVMA would need to educate the community that the regulator has actually recognised different levels of risk in relation to products but until now has not effectively identified that to the public. Either way this will be a major public relations challenge (disaster) for APVMA in engaging the public and retaining/instilling further confidence.

6.1.5 Facilitating access for minor uses

The Alliance has previously submitted its views on this topic in its submission to PSIC (Animal Health Alliance submission to the discussion paper on "*A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals*" - 9 February 2010).

6.1.6 Access to high-risk chemicals

The Alliance strongly supports measures that ensure that only those individuals that have the necessary skills, knowledge and experience have access to high risk chemical products. State schemes that provide access to restricted chemical products (RCPs) following attainment of a set of competencies are supported. Further, these approaches to obtaining access to RCPs should be nationally consistent. The significant human health hazards that RCPs present to individuals exposed to them occurs irrespective of the jurisdiction in which the RCP is accessed.

The Consultation RIS seeks to implement a coordinated national program for control of access and use of high risk chemical products.

The Alliance supports this objective, provided that a consistent requirement for access to these chemical products is obtained across all jurisdictions. Development of required competencies should be determined by the appropriate control of use agency rather than the APVMA.

The Alliance does not support adding functions to the APVMA that are not related to its core business of the risk assessment and registration of veterinary chemical products.

PSIC had for many years sought to develop a list of higher-risk chemical products that would require greater competency to be used. A similar body, or an appropriate delegated authority, could be used to identify and implement additional necessary competencies. The national agency for training, licensing and accreditation identified in Section 5, option 1 of the Consultation RIS would be an ideal body to conduct this activity.

Consideration should also be given to employing self-regulatory and co-regulatory measures to meet this objective. Existing accreditation and training schemes such as Agsafe, Chemcert and SMARTTrain are well placed to implement this measure efficiently and effectively. The current scheme could be modified to adopt additional functions while minimising additional costs for governments (and therefore industry). The likely costs and benefits will be dependent on the governance options chosen, but the Alliance would be willing to work with the Government to ensure that all options, not solely regulatory ones, are examined when seeking to achieve this option.

6.2.3 The precautionary principle

The Alliance cannot support any tenet of incorporating a precautionary principle into agvet chemical legislation. No demonstrable argument has been put forward that the existing APVMA approach to undertaking its transparent, science based risk assessments of veterinary chemical products is flawed. The issues of efficiency and effectiveness of the existing risk analysis activities undertaken by APVMA are separate issues to the point at issue here. As the Consultation RIS notes, the APVMA already takes a conservative and cautionary approach to the risk assessment and registration of veterinary chemicals products.

An express adoption of the precautionary principle has been promoted in several submissions as requiring that registrants should bear the responsibility for 'proving the safety' of veterinary chemical products.

These submissions misunderstand that the precautionary principle is not solely about 'proving safety'. It requires a certain magnitude of harm and recognises that there are economic costs of taking action. Misguided efforts to coopt the precautionary principle as merely a requirement for registrants to 'prove safety' misunderstand that risk assessments conducted by the APVMA do not seek to achieve zero risk, as there is always some level of uncertainty when dealing with complex natural systems and environments. Further, it completely misunderstands that applicants do need to demonstrate with high quality data that the use of their product will not present any unacceptable risks to human health, animals, the environment and trade.

Veterinary chemical product applicants are already required to demonstrate the safety of their products before registration will be considered by APVMA.

6.3 Permissible Uses

The Alliance supports mechanisms that will provide farmers with the tools that they need to produce quality food and fibre. However, like all legal uses of veterinary chemical products, permissible uses on food/fibre animals must be carefully considered to ensure that they do not expose consumers, animals and the environment to unacceptable risks.

The Alliance supports the existing risk assessment processes for veterinary chemical products. This process remains the best mechanism to ensure that all the risks associated with the permissible applications of veterinary chemical products can be safely and responsibly managed. Permissible uses seek to identify a range of situations where veterinary chemical products may be used in a way that is not strictly described upon the product label.

Allowing chemicals to be used in a manner other than that described on a product label has potential liability implications for product registrants should the use result in an adverse event. Further, allowing permissible uses diminishes the value of the data protection that is critical to encouraging innovation, research and development necessary to add new claims onto labels.

6.3.1 General access categories and permits

The three options detailed in the Consultation RIS relate realistically to agricultural chemical product situations. While the permit system offered by APVMA in relation to off label use of registered veterinary chemical products has some relevance to the Alliance members, the presence of the veterinarian in the market place offers a transparent and workable risk management process for legitimate off label use of veterinary chemical products.

6.3.3 Veterinarian's prescribing rights

The Alliance supports a nationally harmonised approach to veterinarians' prescribing rights.

6.4 Management of the chemical portfolio

The Alliance has previously stated its opposition to the proposal for a re-registration system in Australia for veterinary chemical products (Animal Health Alliance submission to the "*Better Regulation of Agricultural and Veterinary Chemicals Policy Discussion Paper*" - 17 December 2010). No demonstrable argument has been presented from government on market failure within Australia in relation to the supply and use of veterinary chemical products. The Alliance wishes to stress that our opposition is based on the facts:

- That it will not generate reductions in risk and will impose significant costs that will ultimately be borne by farmers and pet owners;
- That a re-registration scheme is likely to result in useful chemical products that have been used successfully and within acceptable risk parameters to be withdrawn because of the economic costs of supporting a product through a re-registration process. This is likely to result in re-registration being supported for those products with high sales whereas smaller niche products and generics are more likely to be withdrawn, resulting in reduced competition and less choice and value for farmers and pet owners;
- That a re-registration process will diminish the economic return on investment for new veterinary chemical products by imposing significant additional cost burdens upon the APVMA. Farmers and pet owners will miss out on access to new innovative products if resources and costs are increased to manage re-registration. The concern is that the efficiency and timeliness of new product application review will decrease; and
- There is no policy concern that has been identified that would be resolved by implementation of a re-registration scheme.

The Alliance supports an effective and efficient Chemical Review System.

6.5 Supplier compliance – importers, manufacturers and retailers/distributors

The Alliance supports proposals to provide the APVMA with a complete, modern set of compliance powers. The Alliance has previously observed that the APVMA's compliance tools do not permit it to tailor its enforcement responses to the range of offences that fall within its jurisdiction. Ensuring that the range of compliance tools available to the APVMA reflects its functions as a risk assessor of veterinary chemical products, the compliance tools could be expanded.

Basing the compliance tools upon guidance established by the Attorney-General's Department, and modelled on existing tools employed by other chemical regulators such as the TGA and NICNAS, is appropriate.

The APVMA's compliance functions with respect to retailers and distributors should remain limited. While the APVMA must retain the appropriate tools, industry stewardship programs as well as significant regulatory attention from other regulators (such as the ACCC and Safe Work Australia) mean that there is limited need for the APVMA to extend its functions into the retail sector.

The proposed harmonised national control of use legislation will also increase compliance.

7. CONTROL OF USE

The Alliance supports national approaches to control of use. Irrespective of the governance options chosen, nationally consistent approaches to control of use will benefit industries in meeting their obligations to safely use and handle veterinary chemical products.

Jurisdictional differences in regulations controlling the safe and responsible handling of veterinary chemical products are generally not justified. While some states believe that jurisdictional changes are required to take into account special circumstances, this ignores the fact that farming regions are not bounded by state borders.

Nationally consistent approaches to control of use are needed to protect the integrity of the risk assessments conducted by the APVMA. Accurate risk assessments on a product are confounded when different states allow veterinary chemical products to be used off label (e.g. veterinarians prescribing rights) or by users with different levels of training. As directed by the Productivity Commission, a national system must, at the very least involve 'uniform approaches to enforcing conditions of use on product labels and to the licensing and training of users.'

7.1 Monitoring, Auditing and Surveillance

The Consultation RIS proposes to establish a national program for monitoring residues of agvet chemicals and contaminants in agricultural commodities and the environment, integrated with effective auditing and surveillance.

Significant monitoring and surveillance already occurs through much of Australia for environmental impacts of agvet chemicals/products. In addition, the National Residues Survey regularly demonstrates that agricultural chemical residues rarely exceed Maximum Residue Levels.

Collectively, the current publicly available monitoring data would indicate that most farmers and users are able to use the majority of veterinary chemical products without any adverse impacts on human health, animal welfare, the environment and trade.

The Alliance is concerned that there is no clear statement of the mix of residue monitoring activities that are anticipated should this proposal be adopted. A comprehensive system of environmental monitoring is likely to be prohibitively expensive. While costs may be minimised by adopting a risk based approach, the significant costs of monitoring and testing samples may potentially significantly exceed any benefits in terms of enhanced compliance or reduced environmental risk. Without a clear proposal and a discussion of the likely costs and benefits that would accrue, the Alliance could not support implementation of a comprehensive monitoring system.

However, an approach that uses the results of existing monitoring programs to inform risk-based compliance functions may generate benefits that outweigh costs. Greater assessment of the likely costs and benefits of the various monitoring options should be considered as this option develops further.

The Alliance would welcome greater detail and further consultations with respect to proposals for effective auditing and surveillance to ensure that the benefits associated with any auditing and surveillance scheme are not exceeded by corresponding costs.

7.2 Record keeping

The Alliance supports record keeping as an important part of the responsible use of veterinary chemical products. Care needs to be taken to ensure that the regulatory burden is minimised. Many users of veterinary

chemical products already keep records of use for other reasons or under the requirements of other regulatory or quality assurance schemes.

Careful design of record keeping requirements can significantly reduce the regulatory burden resulting from compliance. For example, under any new record keeping requirements, existing requirements should be recognised. Product users must not be required to keep additional records where these records duplicate ones already kept under other regulatory or stewardship schemes. Further, regulators should not require product users to keep records of information that is freely and publicly available. Finally, product users should only be required to keep the minimal record necessary to allow the regulator to meet the policy objective sought through a record keeping process.

Ultimately, record keeping should only be used to help identify problems associated with veterinary chemical product use. Record keeping should not include mandatory reporting of veterinary chemical product use. Furthermore, if government ultimately pursues this initiative, clear communication to effected parties will be required from government/regulators on what is the intended outcome of requiring record keeping by farmers and what are their rights for data confidentiality in relation to such mandated record keeping.

8. TRAINING AND LICENSING

The Alliance supports proposals to implement nationally consistent competencies for all farm based users of veterinary chemical products. All users must have the skills, knowledge and expertise necessary to manage the potential risks that arise from using such products.

The risks from use arise irrespective of whether a chemical product is being used by a fee for service operator or a farmer. Similar measures must be in place for all users to underpin appropriate product use.

Currently, differences in training and licensing regimes can lead to confusing requirements for product users that operate across state and territory borders, and can hinder the transferability of competencies and licences between states, increasing costs for businesses.

The Alliance considers that an effective training regime must reflect the risks that product users are likely to face. This should result in a graduated scheme where users that apply veterinary chemical products under direct supervision undertake basic training to ensure that they can understand, read and comply with the label directions.

The Alliance believes that apart from licensing users to use high risk identified chemical products, a general user licensing scheme is not justified.

8.3 Sales personnel and advisors

The Alliance is of the view that off label product use presents a significant threat to safe and effective use of veterinary chemical products because:

- It undermines the risk assessment conducted by the APVMA when registering a product;
- Advisors and sales personnel are not able to fully assess the risks when making off-label product use recommendations, potentially resulting in unanticipated or adverse events;
- Consequences of adverse events may extend beyond the area of advice provided; and
- It undermines the incentive for product registrants to develop data to support approval of new uses on product labels.

The Alliance supports proposals to ensure that sales personnel and advisors are appropriately trained to provide useful and valuable advice to farmers to meet their animal health needs. However, that should not

extend to providing advice that farmers should use a product in ways that expose users, consumers, animals, the environment or trade to unacceptable risks.

The Consultation RIS identifies two options for accrediting sales personnel and advisors. These are to:

1. Develop a system to ensure that advisors and sales personnel are competent and make appropriate and legal recommendations; and
2. Recognise industry developed schemes (Agsafe, Chemcert, and SMARTTrain) that train and accredit advisors and sales persons to ensure that they are competent.

The Alliance supports option 2 as likely to generate similar benefits but at considerably lower cost than a regulated scheme. Certain aspects related to training of sales staff within Agsafe accredited premises already occurs. The Alliance would be willing to work with governments to further develop self-regulatory and co-regulatory measures that will address this issue.

Formal recognition by regulators would be required, and supported, to ensure that advisors do not recommend uses of veterinary chemical products that involve unacceptable levels of risk.

The Alliance would welcome further discussion regarding the likely costs and benefits resulting from implementing an accreditation scheme for advisors.

CONCLUSION

Development of a national scheme for the efficient and effective regulation of veterinary chemical products presents a rare opportunity to comprehensively assess the entire regulatory scheme capturing these products. The Alliance welcomes all opportunities for consultation with governments as proposals are developed. It is critical that the outcome of this process, along with other parallel processes examining the best way to regulate veterinary chemical products, must be progressed carefully and thoughtfully. Product registrants and users, along with community groups, need to be fully aware of the costs and benefits associated with each option presented to be able to provide useful and considered feedback to government.

The Alliance expects that further consultations with affected industries and community groups will be required as the costs and benefits of each option are identified. Cost information in particular will be critical to determining what options are likely to deliver the best outcomes for all stakeholders at the lowest cost. While some proposed options may appear to offer benefits in terms of reduced risk or increased efficiency, they may not be adopted in circumstances where their cost far exceeds the likely benefit.

The options contained in the Consultation RIS at this stage require further consideration and discussion of likely costs and benefits. Where appropriate, options for industry self-regulation and co-regulation must also be considered.

It is important that Commonwealth, state and territory governments maintain their commitment to developing a nationally harmonised approach to regulation of veterinary chemicals, products and labels. However, the potential impact upon Australian agriculture of implementing measures that are expensive and ineffective does require that options are carefully considered. It would not be acceptable to waste the current, significant opportunity to address key regulatory issues by failing to follow appropriate consultation and policy development processes.

SUBMISSION - ATTACHMENT 3.

Animal Health Alliance
SOLUTIONS FOR THE FUTURE

Animal Health Alliance (Australia) Ltd
ABN: 76 116 948 344
Address: Level 2 AMP Building
1 Hobart Place
Canberra ACT 2601
Locked Bag 916
Phone: 02 6257 9022
Fax: 02 6257 9055
www.animalhealthalliance.org.au

28 February 2012

APVMA
PO Box 6182
KINGSTON ACT 2604

Alliance response to the APVMA Cost Recovery Discussion Paper

The Animal Health Alliance (Australia) Ltd (the Alliance) is the voice of the animal health industry in Australia. It represents registrants, manufacturers and formulators of animal health products. The association's member companies represent in excess of 85 per cent of all animal health product sales in Australia (ex-factory gate). The Alliance manages both national and state issues with the objective of ensuring its members can operate within a viable regulatory environment. The Alliance also contributes to sustainable industry risk reduction practices that provide business opportunities to members and add value to the broader Australian community.

The Alliance finds it difficult to comment comprehensively to this Discussion Paper since, among other things, details in the APVMA Paper relate to the Better Regulation Bill (Draft Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011 – draft Bill) released for stakeholder consultation which is incomplete as the accompanying draft Regulations are not available for stakeholder review.

As such, the Alliance is handicapped by the lack of full information being made available from government for us to be fully informed. In such an environment the Alliance cannot, in all fairness, give support to any proposed initiatives. The Alliance reserves the right to in future revisit any position or comments it offers on the present Discussion Paper.

The Alliance notes the content of the Discussion Paper (See Attachment A) and acknowledges government policy requiring agencies to review cost recovery arrangements at least once every 5 years. It is difficult however to rationalise what efficiencies will be delivered from this present Discussion Paper when a separate fundamental review of the APVMA cost recovery arrangements will be undertaken over the period 2012 to 2014. This review is proposed to include all aspects of the APVMA's cost recovery arrangements and will be undertaken by DAFF in consultation with APVMA and the Department of Finance and Regulation (piii of Discussion Paper), with a new Cost Recovery Impact Statement (CRIS) to be developed to incorporate changes prior to 30 June 2015 (p9 of Discussion Paper). The chronology proposed here does not support the intent for delivering efficiency for this Federal regulator.

The Alliance confirms its position of 2009 that we support a 100 percent cost recovery of "upfront" fees for APVMA. Only with such a costing approach can full transparency (or confidence) be delivered in this true costing of APVMA registration services to industry. Such 100 percent upfront fees (paid in 2 instalments) can deliver strong incentives for time line efficiencies via quality application submissions from industry, plus efficient and effective use of legislative timeframes by APVMA to deliver assessment outcomes (Alliance [2009]: Response from Animal Health Alliance (Australia) Ltd to the draft Cost Recovery Impact Statement on the Review of Cost Recovery Framework for the APVMA).

The Discussion Paper (p4) highlights that the APVMA is using the cost recovery framework delivered by the Signatories Working Group (SWG) and endorsed by the Primary Industries Standing Committee (PSIC) as its baseline position. The original rationale for the SWG 40/60 percent costing model was that a higher level of cost recovery via an application fee would be a significant disincentive for new products and other innovation into the market, particularly in the case of small businesses and low volume chemical products [APVMA 2005 – Final Cost Recovery Impact Statement on the proposed revised cost recovery framework for the national registration scheme for agricultural and veterinary chemicals (Canberra's Department of Agriculture, Fisheries and Forestry)]. No modelling or justification for this 40/60 percent split was presented to Avcare (then the industry association) at the time it was proposed.

At present APVMA has only been recouping ≈22.15 percent, rather than 40%, of upfront costs as proposed by the SWG (p26 of Discussion Paper). Considering that the SWG 40/60 percent model was proposed over a decade ago now (with credible modeling to unpin it not being offered to industry) and similarly considering that APVMA has never met this 40/60 percent split for its income generation, it appears to the Alliance incomprehensible that now there is a proposal to correct the funding split (almost a decade on from when the 40/60 split was proposed). At the same time there is recognition that the original SWG model is now old and a fundamental review of the APVMA cost recovery arrangements will be undertaken over the next 2 years.

Surely from an efficiency point of view the review should happen now, prior to this CRIS being finalised. In 2 years' time there is the potential for the COAG reforms on harmonisation on the "Control of Use of agvet chemicals" recommendation materialising and another set of financial imposts being targeted at APVMA. The Alliance believes the proposed chronological steps will undermine efficiency delivery in the regulatory operation and process.

The Alliance is similarly concerned that in relation to the proposed continuation process that a 40 percent cost recovery ($700) is proposed in the fee for this service. There is a strong possibility that many existing registered products will not pass the contemporary risk assessment/management process proposed with the continuation process and will lose registration/approval. As such, the residual 60 percent cost of the service for these products will need to be recouped from other registered products via the sales levy. This proposed costing model for the continuation process will drive further cross subsidisation in the APVMA costing model. Rather than instigating a new process and fee that overtly instils a cross subsidisation outcome, the APVMA should be commencing from a "user pays" tenet – especially where the new process is highly likely to deliver attrition in product registration/approval. The present proposed costing structure for the continuation process will not deliver efficiencies from a costing basis.

Yours sincerely

Dr Peter A Holdsworth AM FAICD
Chief Executive Officer
Animal Health Alliance (Australia) Ltd

ATTACHED – Alliance report APVMA Cost Recovery Discussion Paper

ATTACHMENT A

Alliance report
APVMA Cost Recovery Discussion Paper

For period 1 July 2012 to 30 June 2015

The Alliance notes that -

- This is a "discussion paper" on APVMA cost recovery
- A Cost Recovery Impact Statement (CRIS) will be developed in March 2012 and in developing it APVMA will consider comments received on this discussion paper
- The scope of this discussion is for up to 2015 which will cover the time period prior to the Better Regulation Bill actually being operational by APVMA
- The discussion paper proposed to shift APVMA to the agreed 40 percent cost recovery of applications/assessments with the residual cost (60 percent) being recouped via the sales levy
- A proposal is offered for implementing a "user pay" system for non assessment costs such as MLS and Chemical Review and Compliance. In this context an annual fee is proposed of $1,115 per registration for veterinary chemical products which fall under the GMP/MLS system and an annual fee of $620 for registration of agricultural chemical products and non GMP veterinary chemical products. These fees would be phased in over a series of years to be fully operational by 2015
- The differential in the proposed annual fee is due to the existing ongoing costs for the APVMA MLS being grossly underestimated with APVMA actually under recovering between $1-1.5 million per annum to operate the scheme. The un-recouped cost for the GMP veterinary registrations is being cross subsidised by the agricultural chemical registrants
- Accompanying the proposed annual fees would be the cancelling of all existing MLS licenses, the waiver of any outstanding MLS licence fees and the implementation of a new MLS licence for all affected registrants to accompany the new annual fee
- There is a proposal for a $350 fee to accompany the pre-application consultant service to be offered by APVMA out of the "Better Regulation Bill". This single fee would be refunded if the advice offered by APVMA eventually accompanied a future application
- Late payment penalty for annual fees would be increased from $50 per product to $100 per product
- APVMA is considering the possibility of offering an automatic 10 percent refund to applicants of their assessment fee if the APVMA fails to make a regulatory decision on their application within the statutory timeframe
- The proposal is to end up with APVMA recovering 40 percent of cost of assessments up-front and with the residual 60 percent collected via the levy. The implementation of more reflective "user pay" annual fees ($1,115 or $620) will also offer more transparency and means that less reliance is placed on the sales levy to balance the budget. As such, a proposal is offered to reduce the percentage figures in place, relating to the sales levy to reflect less reliance on the levy in the future

- The APVMA proposes an income of $30.361 million in 2012-2013 increasing to $33.005 million in 2014-2015. This should be looked at in respect of APVMA's budget this year of $24 million. (None of these proposed cost increases cover the future likely impact for APVMA from the COAG harmonisation control of use initiatives that, if adopted, would likely start impacting on APVMA in 2015)

- The proposed changes in costing structures for assessment fees and annual fees will decrease the reliance APVMA places on the sales levy to balance its books. The shift is proposed to possibly end up at ≈ 60 percent income for assessment fees and annual fees and ≈ 40 percent from levies

- The paper's purpose is to inform on the development of interim cost recovery arrangement

- The paper concentrates on ensuring appropriate and sustained revenue to enable efficient and effective administration of regulation and to minimise risks whilst the fundamental review of the APVMA's cost recovery arrangement is being undertaken

- The paper encompasses proposed costing and recovery arrangements for existing APVMA function as well as those proposed out of the Better Regulation of Agricultural and Veterinary Chemicals reforms

- A Cost Recovery Impact Statement (CRIS) will be developed in March 2012. The CRIS will consider submissions on this Cost Recovery Discussion Paper

- A separate fundamental review of the APVMA cost recovery arrangements will be undertaken over the period 2012 to 2014. This review will include all aspects of the APVMA's cost recovery arrangements and will be undertaken by DAFF in consultation with APVMA and the Department of Finance and Regulation

The Alliance acknowledges that -

- This Cost Recovery Impact Discussion Paper notes that the changes discussed could lower the APVMA's reliance on the levy from 60 percent to 40 percent of the APVMA total income

- The financial reserve is currently set at three months of operating expenses ($6million in 2011-12)

- At 30 June 2011, the APVMA's equity (excluding unspent one-off Reform Agenda funding) was $5.4 million, which is approximately $0.6 million below its target reserve

- As net expenditure increases, the APVMA would normally increase the financial reserve to ensure it represents approximately three months of operating expenses. This would require it to be increased from its current level of $6 million to $7 million in 2012-13. However, if implemented, the changes outlined in this Cost Recovery Discussion Paper could lower the APVMA's overall reliance on the levy (moving it from 66 percent of total income to around 40 percent of total income) allowing the APVMA to reduce the reserve to two months of operating expenses for the period 2012-2015. This will allow the reserve to be maintained at around $6 million and not increased over the period 2012-2015

- In 2010-2011, the levy on wholesale product sales represented approximately 66 percent of the APVMA's total revenue. For the financial year 2010-2011, a total of 843 companies renewed registrations on a total of 9,551 agvet chemical products, and the majority of these companies (770) had sales of less than $5 million.

    — Of 843 companies with registered agvet products, 176 companies had all products with zero product sales
    — Another 594 companies had sales of less than $5 million
    — The 594 small companies had a total of 3,814 products registered

— The average product sales for small* companies was $93,000
— The average product sales for medium* companies was $199,000
— The average product sales for large* companies was $686,000

* **Small company** – wholesale agvet chemical product sales of less than $5 million a year
Medium company – wholesale agvet chemical product sales of between $5 million and $20 million
Large company – wholesale agvet chemical product sales of greater than $20 million a year

- Agricultural companies are 72 percent of companies with registered products and their products represent 65 percent of the total number of products registered by the APVMA. The average annual sales per company are comparable whilst the annual average sales per product are higher in agricultural companies than veterinary companies

- Sales of most products are relatively low because Australia is a small market in global terms. About half of the products (in 2010-2011) in the market earn less than $25,000 in sales, and more than a third of the registered products have no sales. The majority of these products continue to record nil sales in subsequent years; that is, the APVMA does not recover 60 percent of the cost of the application

- The wholesale value of veterinary product sales tends to be relatively stable, whereas the wholesale value of agricultural product sales is more tightly linked to domestic conditions. The baseline (2009-2010) ratio of agricultural to veterinary product sales is 2.61 : 1. The APVMA has identified that, in previous years, the ratio has been as high as 3.65 : 1. The effect of such a ratio change on the levy revenue could be as much as $5 million, highlighting the importance of reducing the reliance on the le vy as a source of revenue

The Alliance recognises that -

- In early 2011 the Biosecurity Services Group – Food Division of DAFF, advised the APVMA that in their view the specific regulations governing the HGP Open Scheme was no longer required to sustain European Market (EU) access. DAFF is working with other interested stakeholders to confirm wider concurrence that full reliance on the closed EUCAS system, in preference to the HGP Open Scheme, is appropriate which may then lead to a formal recommendation to rescind the specific HGP regulation

The Alliance reads that in relation to Cost Recovery APVMA proposes -

For 3.2 Existing arrangements improvements

- The existing cost recovery arrangements documented in the 2005 CRIS should be improved. This is evidenced by the following:

  — Cost recovery for product evaluations is well below the 40 percent recovery rate for upfront application fees (the cost recovery rate is currently averaging around 24.7 percent with the remainder recovered through the levy)

  — MLS Licence fees that have resulted in under-recovery of GMP activity costs in the order of $1.1 million (in 2007-2008)

  — There is currently a high reliance on levy revenue that, because of fluctuations in agvet chemical sales due to climatic variations, results in large fluctuations in the APVMA's revenue base

- The APVMA proposes to return all application fees to the Signature Working Group's 40 percent target level. To cushion this increase, it could be returned to 40 percent in two phases –
  — Phase One – an increase of all fees to 30 percent of the cost of undertaking the associated activities in the first year (from 1 July 2012)
  — Phase Two – an increase of all fees to 40 percent in the second year (from 1 July 2013)

For 3.3 Legal requirements

- The legislation already provides the framework to enable implementation of the cost recovery changes. The proposed changes will amend specific details such as the amounts charged for fees, or relevant dates without altering the intent or context of the legislation. The key exceptions include:

  — The ending of current MLS licence fees and the implementation of the new licence fee structure
  — Proposed waiver of outstanding MLS licence fees
  — Provision for the indexation of a number of fees

For 3.4 Indexation

- The APVMA proposes to index all fees annually (annual fee, application fees for registration and approval, Certificates of Export and HGP notification number and renewal) to ensure that fees remain cost reflective over time

- It is proposed that indexation for application fees applies from 1 July 2014, one year after fees have returned to 40 percent of the cost of the assessment. Indexation for other fees and charges will apply from 1 July 2013 (12 months after the commencement of any new cost recovery arrangements)

- Fees will be rounded to the nearest five dollars

For 3.5 Registration and Approvals

- Key components of possible changes to application fees discussed in this paper include:

  — Moving all application fees to at least 30 percent cost recovery from 1 July 2012 and 40 percent from 1 July 2013, with the remainder of the costs to be recovered from the levy

  — Introducing a new Fee for Consideration set at 40 percent of the cost of administrative and technical evaluation and assessment of applications for continuation

  — Applying 100 percent cost recovery for approval of an active constituent (Category 17 only)

  — Fees for permits to remain largely unchanged (only indexation will be applied) where it can be documented that an increase in expenses have occurred for this activity

  — Maintaining a nil fee for Category 33 (emergency use permit) applications (cost to be recovered through the levy)

  — Indexing all application fees each year on the basis of 75 percent WPI and 25 percent CPI to ensure fees are cost reflective over time from 1 July 2014

- It is proposed to maintain the modular fee structure and the APVMA will establish a recovery rate of 30 percent of the cost of the evaluation from 1 July 2012 and then 40 percent of the cost of the evaluation from 1 July 2013

For Pre-application guidance (for product or active constituent)

- A fee of $350 charged for the provision of advice to applicants. The fee includes written guidance in response to applicants' queries for their application, guidance on completion of the necessary application form(s) and advice on data requirements. The APVMA's response to the query will be considered to conclude the service. Any further discussion of the query will attract an additional fee ($350)

- Where the query relates to a future application, and the applicant subsequently submits an application directly related to the advice, only the initial fee ($350) will be refunded against the cost of the application

- A fee of $350 charged for each and every subsequent request for guidance (on completion of the necessary application form). This additional fee is not refunded

Fee rebate

- The APVMA is examining the possible introduction of new arrangements to automatically refund to applicants 10 percent of the cost of the original application fee if the application is not finalised within the specified statutory timeframe

- Category 13 applications
  Cost recovery via the sales levy

- Category 15 and 16 applications
  Cost recovery via the sales levy

- Category 17 (imaged / "me too" active constituent application)
  Recover 100 percent of cost of processing the application in up-front fee

- Category 18
  Combination of fee and levy to continue

- Category 19 – 21 (permits)
  - Retain present system of fee and levy to recovery costs
  - Commonwealth and states/territory government agencies will continue to pay fee for their permits where it provides a significant commercial benefit to that organisation

- Category 22
  Nil fee and rely on sales levy

- Category 23 (research permit)
  Fee charged up-front at 100 percent of cost based on modular fees

For evaluation of applications for continuation (re-registration)

- It is proposed to retain a split to ensure that the cost of continuation is no more than the cost of initial registration (especially in case of category 8 (repack) applications

For evaluation of applications for GMP

- Proposed to introduce a specific annual fee to recover the full cost of a GMP Scheme from these veterinary companies that participate in the scheme. Non GMP veterinary products would be charged at lesser amount

- MLS licence fees would be abolished and all outstanding liabilities for these fees would be waived. New licences would be issued without charge to the applicant. The cost of GMP will be recovered through the use of a new annual fee which will be payable by all registrants who have products that are required to be formulated at licensed premises. This fee will be specified through an appropriate amendment to the Agvet Code Regulation

For proposed MLS Licence Fees

- All agricultural products and non GMP veterinary products ($620 in 2014-2015); under this category all registered agricultural products and non GMP veterinary products pay an equal share towards the costs of investigation and enforcement, Chemical Review and the AERP (excluding Continuation Scheme costs where advice of fee is supplied)

- GMP veterinary products ($1,115 in 2014-2015); under this category all GMP veterinary products pay an equal share towards the costs of investigation and enforcement, Chemical Review and the AERP (excluding the Continuation Scheme costs) and the specific costs of the GMP scheme

- Certificates of export
  Direct fee to users of service

- Consent to import
  No direct fee charged

For 3.6 Monitoring ongoing compliance with regulation

- HGP product suppliers to pay an annual fee

- Quality Assurance Scheme for agricultural active constituents and agricultural chemical products – pay an annual fee ($620 above)

- Adverse Experience Reporting Program and Chemical Review
  - Pay an annual fee of either $620 or $1,115 per product (see above)

For 3.7 Investigation and Enforcement

- Pay an annual fee of either $620 or $1,115 per product (see above)

For 3.8 Information activities

- Fees and charges for specific activities

For 3.9 The annual fee

- $620 per product or $1,115 per product (see above)

- In some circumstances, especially for low selling, but important veterinary products that must be maintained, a concessional fee may be appropriate. APVMA proposes to introduce arrangements to allow registrants to apply for a concessional annual fee of $430 where:

  - The product is on the market and being sold
  - There are a limited number of alternative products
  - Sales are very low

- It would be necessary to phase in the implementation of the annual fee. To this end, a combination of the annual and levy could be applied to cover the cost of post market activities in 2012-2013 (the annual fee would remain at $430) and the new annual fee model would be introduced in 2013-2014. To soften the impact of funding the cost of the GMP Scheme via the annual fee charges on GMP veterinary products, it is proposed that a 20 percent discount is given to those products in 2013-2014. The fee will be 100 percent of the cost in 2014-2015

- The APVMA proposes that both annual fees are indexed each year based on 75 percent WPI and 25 percent CPI (reported in December of the previous year) to ensure fees are cost reflective over time

- Late payment of the annual fee is proposed to be increased from $50 to $100

For 3.10 The Levy

- APVMA proposed to retain the levy model that has previously operated until the fundamental review by DAFF is completed

- The increase to the annual fee(s) would allow changes to be made to the tiered levy model as follows:

The proposed levy rates for 2013-2014 are:

TABLE 1: LEVY RATES

LEVY PAID IN	2011–12	2012–13	2013–14	2014–15	2015–16
BASED ON SALES DURING	2010–11	2011–12	2012–13	2013–14	2014–15
Levy tier 1	0.80%	0.75%	0.57%	0.57%	0.57%
Levy tier 2	0.45%	0.43%	0.30%	0.30%	0.30%
Levy tier 3	0.30%	0.29%	0.15%	0.15%	0.15%

Tiered levy thresholds are based on:

- no levy is collected for annual product sales up to $5 000 (as it is not efficient to do so)
- levy tier 1 rate for annual product sales up to $1,000,000
- levy tier 2 rate for additional annual product sales between $1,000,001 and $5,000,000
- levy tier 3 rate for additional annual product sales greater than $5,000,000.

The increase in application fees and the use of the annual fee(s) to recover most post-market activities would allow the levy rates to be reduced in the proposed levy rates. The levy rate changes would be implemented by an amendment to the rates specified in r.6A(2) of the *Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995*.

An additional charge currently applies for late payment of the levy: (i) $200 for unpaid levy less than $10,000; or (ii) $400 for unpaid levy greater than $10,000. There is an additional penalty for understatement of disposals. Both of these penalties would continue.

For 4.4 Periodic Review

- APVMA will complete another review of its cost recovery arrangements within the next three years (by 30 June 2015)

SUBMISSION - ATTACHMENT 4.

Animal Health Alliance
SOLUTIONS FOR THE FUTURE

Animal Health Alliance (Australia) Ltd
ABN: 76 116 948 344
Address: Level 2 AMP Building
1 Hobart Place
Canberra ACT 2601
Locked Bag 916
Phone: 02 6257 9022
Fax: 02 6257 9055
www.animalhealthalliance.org.au

29 February 2012

Agvet Chemicals – Early Harvest and APVMA Reforms Team
Agricultural Productivity Division
Department of Agriculture, Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601

Alliance submission to the
Better Regulation of Agricultural and Veterinary Chemicals Regulation Impact Statement

The Animal Health Alliance (Australia) Ltd (the Alliance) is the voice of the animal health industry in Australia. It represents registrants, manufacturers and formulators of animal health products. The association's member companies represent in excess of 85 per cent of all animal health product sales in Australia (ex factory gate). The Alliance manages both national and state issues with the objective of ensuring its members can operate within a viable regulatory environment. The Alliance also contributes to sustainable industry risk reduction practices that provide business opportunities to members and add value to the broader Australian community.

The Alliance appreciates the opportunity to provide input into the Better Regulation of Agricultural and Veterinary Chemicals Regulation Impact Statement (RIS).

The Alliance is encouraged to read in the first section of the RIS (section 1.2, p2) the reinforcing of APVMA's role and responsibility, among other things, is to make evidence based evaluation and approval of active constituents and the registration of agvet chemical products.

All Alliance comments supplied here are tabled on the understanding that the accompanying Regulations for the proposed Bill have not yet been released, nor discussed with industry in any form, at the time of writing this submission. The Alliance is particularly concerned with the lack of a comprehensive data package being made available to industry for this consultation process. The continual elaboration by the Department of Agriculture, Fisheries and Forestry (DAFF) and the Australian Pesticides and Veterinary Medicines Authority (APVMA) on the RIS throughout the three month stakeholder consultation period has left the Alliance feeling extremely uncomfortable in offering comment. With no draft Regulations available and uncertainty of DAFF/APVMA final interpretation/operation of the draft Bill, the Alliance is unsettled with this total consultation process.

The Alliance strongly believes that further progress on this draft Bill should cease until the accompanying Regulations have been drafted and released for industry consideration and that consideration has been dealt with through a true comprehensive consultation process. Our rationale for this position is that the accompanying Regulations to the draft Bill have not been made available to industry to date and that the interpretation of the operation of sections of the draft Bill have shifted from what appears in the discussion document dated November 2011 to what appears on APVMA Risk Framework Reform documentation of January/February 2012.

The Alliance reserves the right to revisit any or all of its comments within this submission, based on the content of future drafted Regulations to accompany this draft Bill along with any future interpretation/re-interpretation of the draft Bill by DAFF/APVMA.

Yours sincerely

Dr Peter Holdsworth AM FAICD
Chief Executive Officer
Animal Health Alliance (Australia) Ltd

ATTACHMENT 1 Cost of Diseases
ATTACHMENT 2 Errors/inconsistencies in the Agvet Chemical draft exposure Bill

Animal Health Alliance (Australia) Ltd

Submission to the

Better Regulation of Agricultural and Veterinary Chemical Regulation Impact Statement

Contents

EXECUTIVE SUMMARY

- The Alliance comments are structured for clarity based on the five "Measure groups" used in the "Better Regulation of Agricultural and Veterinary Chemicals" Regulation Impact Statement (November 2011)

- The Alliance supports any initiatives that deliver improvement to efficient, transparent, science-based decision making within the National Registration Scheme

- The Alliance expresses concern in the shift in interpretation of particular contents of the draft Bill within DAFF and between DAFF and APVMA as the 3 month stakeholder consultation period has progressed. This in reality only left the Alliance with 4 weeks (being February 2012) when all documentation from APVMA (APVMA Risk Analysis Framework November 2011; APVMA Continuation Framework Discussion Paper January 2012; APVMA Overview of APVMA Operations and Future Directions – A Tool for Business Reform January 2012) was released to industry and industry could collate the shifts in the position offered in the explanatory notes to the draft Bill (dated November 2011) versus the APVMA position in the documentation

- The Alliance believes it is time for developing and implementing a 2 tiered regulatory structure and process within APVMA – one for agricultural chemicals and one for veterinary chemicals. Each structure and process should be costed out and this should be reflected in the fees and charges imposed on product applicants and registrants. This exercise should further recognise the existing regulatory processes already operating for veterinary chemical products within the APVMA (e.g. pharmacovigilance / AERP; manufacturing licensing scheme etc) and reflect these existing risk mitigation processes in the operation and costs imposed on the veterinary chemical industry. This Regulation Impact Statement has clearly identified the differences in regulatory processes and activities needed by APVMA to manage risk for agricultural chemicals compared to veterinary chemicals. The time is right to acknowledge that a "one size fits all" agvet chemical regulator no longer serves the best interests of the veterinary chemical industry

- The Alliance strongly believes considering the accompanying Regulations to the draft Bill have not been made available to industry to date, and also considering that the interpretation of the operation of sections of the draft Bill have shifted (from what appears in the discussion document dated November 2011 to what appears on APVMA Risk Framework Reform documentation of January/February 2012), the progress of this draft Bill should cease until the accompanying Regulations have been drafted and released for industry consideration and that consideration has been dealt with through a true comprehensive consultation process

INTRODUCTION

The Animal Health Alliance (Australia) Ltd (the Alliance) is the voice of the animal health industry in Australia. It represents registrants, manufacturers and formulators of animal health products. The association's member companies represent in excess of 85 per cent of all animal health product sales in Australia (ex factory gate). The Alliance manages both national and state issues with the objective of ensuring its members can operate within a viable regulatory environment. The Alliance also contributes to sustainable industry risk reduction practices that provide business opportunities to members and add value to the broader Australian community.

The Alliance appreciates the opportunity to provide input into the Better Regulation of Agricultural and Veterinary Chemicals Regulation Impact Statement (RIS). The effect of the proposed reforms has the potential to significantly impact on the future way Alliance member companies invest and operate in Australia. It is imperative that the Australian veterinary chemical regulatory environment operates to world's best regulatory practice. It needs to be underpinned by evidence and science based decision making, operating in a transparent, efficient and effective manner. The Alliance has in the past provided a submission (see ATTACHMENT 1) that quantified the cost of disease to Australian primary production plus the impact of inefficient regulation to industry in disease control. Clear cost/risk benefit analyses are needed to justify and underpin any new regulatory imposts on industry and similarly with amendments to existing regulatory burdens.

The Alliance is encouraged to read in the first section of the RIS (section 1.2, p2) the reinforcing of APVMA's role and responsibility, among other things, is to make evidence based evaluation and approval of active constituents and the registration of agvet chemical products.

The Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendments Bill 2011 (216 pages); the RIS (48 pages) and the Exposure Draft Explanatory Guide (56 pages) need to be read in conjunction with the Agricultural and Veterinary Chemicals Code Act 1994 (401 pages); the Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994 (52 pages); the Agricultural and Veterinary Chemicals (Administration) Act 1992 (136 pages). With such a volume of documentation underpinning the Better Regulation proposal, it is not surprising that some errors/inconsistencies have slipped into the released papers. The Alliance has earlier supplied comment on such errors/inconsistencies (see ATTACHMENT 2).

The government announced intent of these proposed reforms to aim at cutting unnecessary red tape and encourage development of safe and more modern chemicals is acknowledged. This forms the basis of the Alliance's comments detailed here. The Alliance does however seriously question whether the package proposed here by government can deliver the intended outcome in the most cost effective way.

All Alliance comments supplied in this submission are tabled on the understanding that the accompanying Regulations for the proposed Bill have not yet been released, nor even discussed with industry in any form, at the time of writing this submission. The Alliance reserves the right to revisit any or all of its comments within this submission, based on the content of future drafted Regulations to accompany this draft Bill.

The content of the Alliance submission is structured, for clarity, based on the five "Measure groups" used in the RIS dated November 2011 that accompanied the exposure draft Bill.

MEASURES GROUP 1

Enhance the consistency, efficiency and transparency of agvet chemicals, approvals, registration and reviews.

Group 1 proposals all are underpinned by the APVMA developing and publishing by the end of 2011 an overarching risk framework capturing its risk culture. Subsequent to this, APVMA is to work with its key agency advice providers, to develop detailed documents on the risk framework used in the assessment processes conducted by these agencies. These framework documents, plus any operational/scientific documentation, guidelines etc are to be published. This will require APVMA to review/amend MORAG, requirements and guidelines already in the public domain so to ensure these documents remain contemporary and relevant to the developed risk framework documents. The intent is these frameworks will drive transparency and clarity in understanding the regulator's risk culture. This, with other announced initiatives here, should drive efficiencies/effectiveness/transparency and build confidence not just with stakeholders but also within APVMA and with its agencies. It is not anticipated that these exercises will be completed and ready to be implemented before the end of 2013.

The Alliance acknowledges the intent and activities proposed here. If effectively delivered, these measures offer significant benefits for industry and the regulator.

MEASURES GROUP 2

Ensure the ongoing safety of agvet chemicals and improving the effectiveness and efficiency of current agvet chemical review arrangements, by implementing a mandatory tiered re-registration and re-approval regime, designed to minimise impacts on affected businesses.

Group 2 proposals establish sunset provisions for the approval of active constituents (and labels?) and registration of agvet chemical products. The proposal is to create a 3 tier re approval/registration process that will operate from higher to lower risk products with all active constituents and products re-approved / registered under the tier approach at least once every 10 years. This re-approval/registration process is separate to the annual renewal process for each registered product. Both processes will run in parallel. The 3 tier process is aimed to run on a risk base approach with tier 1 being administrative (the registrant answers set questions about each product); tier 2 being technical based (if the answers offered in the tier 1 process raise concerns in relation to an active constituent/product then any existing data will be sought to address the concerns) and finally tier 3 which is to pass an active constituent/product to the chemical review process (to be placed on the priority list there for ultimate reconsideration) if issues still remain to be resolved.

To assist the APVMA to be in a position to accommodate potential new candidate active constituents/products entering the Chemical Review process the Commonwealth is to allocate APVMA funds (amount not indicated) to expedite dealing with the backlog already existing in the Chemical Review program. The 3 tier re-approval /registration process will operate on a fee for service basis. It is further proposed that the intervals between subsequent re-approval/registrations will range between 7 to 15 years. For this to operate the APVMA risk framework documents need to be in place. As such it is unlikely to commence operation before the end of 2013.

It is argued that this initiative, in combination with others, will over time, remove products from the APVMA register that are not being marketed. It is further argued that this outcome will free up APVMA resources so it may become more efficient. The 3 tier re-approval/registration process is also argued to bring APVMA into line with overseas contemporary regulators, appease community concerns and finally solve for the APVMA the existing problem of having to regulate products it inherited from the State systems in 1994 where no supporting data accompanied those product transfers. The tier approach is expected to operate on an assumption that around 10% of registered products would be assessed under tier 1 in the first year of operation which equates to around 1,000 products. An assumption is then made that 10% of this 1,000 would fall ultimately into the tier 2 process (100 products) and then 10% of these would end up in tier 3 (10 products). No data/modelling is offered to support these assumptions.

The Alliance notes that the position presented here in the draft Bill is at odds with the proposed operational process ultimately communicated by APVMA in the “Continuation Framework Discussion Paper January 2012” (p24). Such inconsistences do not instil confidence in the process for the Alliance.

It is acknowledged that this tier process may have a disproportional impact on generic products over time (especially tier 3) and strategies to mitigate this are being considered (none were articulated). It is further acknowledged that the proposed amendments to data protection (DP) provisions would provide registrants with an avenue to recoup costs.

The Alliance finds it interesting and frustrating to note that the arguments presented in the RIS for the tier 3 process are all based on overseas pesticide regulators (EU and USA). The RIS is silent on veterinary chemical product regulation overseas. The Alliance demands valid justification is presented to support the tenant here that veterinary chemical product regulators must automatically comply with the proposal put forward here in relation to agricultural chemical products.

The Alliance believes it is time for developing and implementing a 2 tiered regulatory structure and process within APVMA – one for agricultural chemicals and one for veterinary chemicals. Each structure and process should be costed out and this should be reflected in the fees and charges imposed on product applicants and registrants. This exercise should further recognise the existing regulatory processes already operating for veterinary chemical products within the APVMA (e.g. pharmacovigilance / AERP; manufacturing licensing scheme etc) and reflect these existing risk mitigation processes in the operation and costs imposed on the veterinary chemical industry. This RIS has clearly identified the differences in regulatory processes and activities needed by APVMA to manage risk for agricultural chemicals compared to veterinary chemicals. The time is right to acknowledge that a “one size fits all” agvet chemical regulator no longer serves the best interests of the veterinary chemical industry.

MEASURES GROUP 3

Introduce reform measures to improve the efficiency of the application process for agvet chemical approvals and registrations, and improve the timeframes of agvet chemical approvals, registration and chemical reviews, including legislation where necessary.

Group 3 proposals are based on improving APVMA efficiencies in dealing with applications. What is targeted here is poor quality applications. Proposals offered include a "one off" per product up front assistance opportunity from APVMA to offer pre application advice. The cost to APVMA of this service would be offset by an equivalent reduction in the application fee for any applicant that relied on this assistance. The RIS argues that this service is likely to benefit small sized applicants with little experience and that larger companies are not likely to use this service often. No data/modelling is offered for this assumption.

To augment this initiative, APVMA will limit its initial assessment of applications to an administrative check on lodgement before accepting and passing on the assessment or rejecting the application.

Complementary changes are proposed here that would require APVMA to reject an application for approval/registration if it is found to be deficient in the initial assessment, or if it cannot be corrected in a reasonable time frame, or where an applicant has not corrected deficiencies in accordance with an APVMA request, with fees paid forfeited.

The Alliance notes an important initiative included here is the intent to introduce statutory time periods for APVMA to complete a review. This intends to cover all stages of the consideration and assessment process in the statutory periods for determining applications for approval or registration or for completing a review. The original support the Alliance offered to this initiative is now negated in reading the APVMA Cost Recovery Discussion Paper (for period 1 July 2012 to 30 June 2015) where APVMA is contemplating offering an automatic 10% refund to applicants on their assessment fee if the APVMA fails to make a regulatory decision on their application within the statutory timeframe. The Alliance finds this APVMA proposal unacceptable. The Alliance believes a statutory timeframe must mean a timeframe by which a regulatory decision will be made. If this is not upheld, then the intent of statutory timeframes in delivering predictability and efficiency disappear.

Other proposals to supplement this initiative include establishing set timeframes for applicants to submit information or to correct deficiencies as requested by APVMA. Similarly it is intended to mandate that any extensions to set timeframes be mutually agreed by APVMA and the applicant. If not agreed the APVMA makes the application decision based on the data supplied at that time. The Alliance is not averse to this proposal only if statutory timeframes are consistently adhered to.

These initiatives should move us away from the focus on "clock on" "clock off" and get APVMA and applicants to focus on an understood defined time for an application/review to be finalised. The Alliance interpretation of the rationale here is to move to a focus on a "single elapsed timeframe" in which APVMA must determine an application/review. This would comprise a minimum timeframe that applies where APVMA does not require the application to be rectified and a maximum timeframe that applies where rectification by the applicant is required. The intent is to permit the applicant and APVMA to negotiate on more than the minimum timeframe BUT this cannot impact on meeting the defined maximum elapsed timeframe.

The Alliance challenges this assumption in the RIS that only small sized companies with little experience will use the APVMA upfront assistance opportunity for pre-application advice. Based on the poor quality of service/transparency and lack of predictability experienced by many Alliance member companies in dealing with APVMA and considering that the cost of the service should be neutral on the applicant (with equivalent reduction in application fee for those who use the service) then why wouldn't any company take advantage of a service that could offer some predictability in dealing with APVMA?

The RIS also proposes to modify statutory arrangements for reconsideration of decisions taken by APVMA where necessary to support the earlier proposal in the RIS of permitting APVMA to reject applications if found to be deficient in the initial assessment. The aim here is to close a loophole of section 161 of the legislation where applicants can "legally" keep supplying additional data to an application after it is submitted and being assessed. The Alliance is not opposed to the intent here.

Finally, this section of the RIS proposes DP provision amendments in relation to data submitted in relation to an application. The aim here is to allow applicants to retain potential DP on data supplied with an application where that application does not receive an APVMA grant. DP provisions would be amended so that where data submitted to APVMA in relation to an application that is not granted and then the data is resubmitted and relied on in relation to a subsequent application that is granted by the APVMA, it would be eligible for protection. The operation of this process could have major resource implications for APVMA in managing submitted data. That aside, the Alliance is sympathetic to the proposal.

A proposal is also articulated to require electronic lodgement of applications and supporting documentation as far as possible and to be implemented in a phased in process. The Alliance supports this intent.

The proposal here also covers DP provision amendments and the following proposals are noted:

- Expand the coverage of the existing 3 year DP for veterinary chemical products for "value adding" so to cover now companion animal products as well as food/fibre producing animal products;
- Expand the coverage of the type of potential data to be considered for DP in an APVMA Chemical Review to include efficacy data in relation to reviewed products; and
- Expand the DP provisions for active constituents/veterinary chemical products placed under APVMA Chemical Review to a maximum of 8 years DP (compensatory DP) with DP commencing from when the APVMA receives requested data and continuing for a maximum of 8 years from when the APVMA makes its first determination on the Chemical Review. [At present DP is up to 7 years compensatory and it commences from when the APVMA receives the requested data].

The Alliance supports these proposed amendments.

MEASURES GROUP 4

Introduce reform measures to improve the ability of the APVMA to efficiently administer its regulatory decisions to protect human health and safety and the environment, including legislation where necessary.

Group 4 proposals cover giving APVMA a graduated range of enforcement powers to improve and streamline evidence collection etc. In addition it is proposed to enhance the existing controls over active constituents and products to ensure their ongoing quality and integrity by providing for updateable conditions of approval or registration. This approach will be guided by the yet to be developed APVMA risk framework. A possible concern identified in the RIS is a proposal to add to the areas that APVMA needs to be satisfied on in relation to licensing of manufacturing sites to include "animal welfare". (Proposed inclusion in section 126 "Conditions of licences" and section 127 "Suspension and cancellation of licences" of the Agricultural and Veterinary Chemicals Code Act 1994).

The Alliance supports the intent here in principle, but reserves the right to reconsider its position based on the detail ultimately revealed. The present proposed wording in the RIS indicates in relation to whether a manufacturing licence should be suspended/cancelled or what conditions should be placed on a licence and that the issue of "imminent risk to animal welfare" needs to be considered in making a decision. There is no definition existing at present in the APVMA legislation or regulations as to what "animal welfare' will be defined as. A similar concern relates to where APVMA would source its expert advice on animal welfare if this proposal is adopted.

MEASURES GROUP 5

Limit opportunities for criticism and improve administrative efficiency by transferring the levy collector's task from APVMA to another Commonwealth agency, including, where necessary, should it be cost effective to do so. This measure would be finalised between the Minister for Finance and Deregulation and the Minister for Agriculture, Fisheries and Forestry.

Group 5 proposals offer the provision, taken at Ministerial level, if desired in the future to transfer the levy collection task from APVMA to another Commonwealth agency, including legislation where necessary, should it be cost effective to do so. It is reported that it costs APVMA around $20,000 per annum in audit fees related to collecting the levies. The proposed Bill also offers wording that if another agency collected the levy for APVMA in the future the APVMA would be required to pay a service fee to that agency for that activity. Argument is also put up in the RIS that if APVMA did not directly collect the levy then possibly community groups would be less concerned about the perception of APVMA being capture by the industry it is regulating.

The Alliance wishes to see further analysis of the rationale and justification for such a shift if proposed in the future.

Other proposals aim to remove redundant provisions of the Agricultural and Veterinary Chemical Levy Act 1994 and the Agricultural and Veterinary Code Act 1994.

The Alliance is not opposed to this proposal.

ATTACHMENT 1

Cost of Diseases

Prepared by

John Lloyd – Menari Business Solutions

15 December 2008

Contents

Executive Summary

Diseases of production animals cause major economic loss to Australian agriculture. Such diseases in beef cattle, dairy cattle, sheep, swine and poultry are usually controlled by the provision of nutritional supplements and/or the application of medicinal or biological agents to either prevent or alleviate the condition. Producers rely upon scientific advances to provide timely and cost effective solutions for the treatment of diseases and conditions, allowing downstream industries involved in the production of food and fibre to compete effectively in both domestic and international markets.

The disease landscape is ever changing, therefore any restriction or delay in the availability of modern animal health solutions will result in an economic impact for producers, as well as the competitiveness of downstream processing industries. This is especially true when such solutions are available in competitor countries, but are either not available or suffer delayed entry in the domestic market.

Animal Health Alliance (Australia) Ltd, ("the Alliance"), representing the majority of animal health companies present in the Australian market (by $ sales), wishes to more fully explore and understand the costs to Australian industry of major production animal diseases, as well as the additional costs incurred or opportunities foregone due to the absence or delayed entry of veterinary medicines/biological available elsewhere.

Menari Business Solutions (MBS) was commissioned to conduct a study evaluating the cost of disease in the Australian production animal industries. The major objective of the study was to fully analyse the costs associated in treating the major diseases of the beef, sheep, swine, poultry and dairy industries as well as understanding the associated production loss to farmers and producers when such diseases occur.

In light of this quantification, MBS was also asked to evaluate the current regulatory environment so as to understand the gaps and opportunities that exist in the products available to Australian farmers, particularly with respect to similar competitive markets such as New Zealand.

The study was conducted utilising existing data sources gained through extensive literature searches, recalibrated and updated where necessary. Where no data source existed in the literature, expert co-operators were sought who were asked to provide specific analyses regarding losses through various diseases.

MBS also extensively interviewed research and regulatory staff in the majority of Australian animal health firms, as well as representatives of industry bodies, research organisations and experts in private consultancy. To gain some perspective with regards the Australian regulatory environment, key staff from the New Zealand Food Safety Authority and Agcarm (NZ), were also personally interviewed.

Members of the Animal Health Alliance were also surveyed in order to understand the effect of regulatory delays or barriers to the introduction of innovative products to the Australian market. Measures of innovation were given as guidelines to classify products, and experienced personnel were asked to estimate reasonable timelines based on experience, risk and overseas standards.

Where losses and costs attributable to a condition arising from a disease or group of diseases have proven to be more quantifiable, then that condition is included.

Loss of production can often be attributable to nutritional, environmental or other non- disease causes. Such cases have been largely excluded from the study unless the data confirms such losses arise from primary disease. Infrequent or irregular catastrophic losses, especially in intensive industries, have also been excluded.

Quantification of Disease

Disease losses, prevention and treatment are major costs to the animal production and processing sector of the Australian farming community. Each year producers of beef, sheep, wool, pigs, eggs, chickens and dairy products face production losses of $936 million due to disease. They incur $819 million in additional expenses in an attempt to either prevent or treat disease outbreaks.

The most important industry from a disease perspective is sheep production which has a combined cost of loss and treatment of $761 million, followed by beef production at $509 million, dairy at $275 million, poultry at $109 million and pigs at $101 million.

The major diseases/conditions include external parasites of sheep and cattle ($562 million); gastro intestinal parasites in sheep and cattle ($328 million); mastitis in dairy herds ($141 million) and footrot in sheep ($109 million). Reduced income includes losses from both clinical and sub clinical manifestations of disease. Increased expenses include both preventative and corrective treatment, and where possible, associated costs such as labour and management.

Table 1 – Losses and Costs from Disease in Major Production Industries (2007 est)

	Reduced Income	**Increased Expenses**	**Total**
Industry	$	$	$
Beef Cattle	303,810,939	204,769,377	**$ 508,580,316**
Sheep	382,675,176	377,221,327	**$759,896,503**
Dairy Cattle	176,691,000	98,780,000	**$275,471,000**
Layer Poultry	9,192,300	25,800,000	**$34,992,300**
Broiler Poultry		73,902,600	**$73,902,600**
Swine	62,120,500	38,896,000	**$101,016,500**
Total	**$934,489,915**	**$819,369,304**	**$1,753,859,219**

Regulatory Environment

As evidenced above the cost of disease treatment and loss is significant in the national economy. Despite some 40 years of progress and scientific innovation, production losses from disease and pests still cost Australian farmers close to $1 billion per annum.

Farmers rely upon innovative products to tackle the challenge of disease. Timely availability of such products contributes to the competitiveness of industry, particularly when that industry is exposed to international competition. This is particularly true for our export oriented industries such as beef, dairy, sheep, meat and wool, where competitors with access to more efficient means of production gain significant advantage.

A report into the animal health industry conducted by Business Decisions Ltd (2007) commissioned by the Alliance and the International Federation for Animal Health observed that the establishment of the Australian Pesticides and Veterinary Medicines Authority (APVMA) would provide an efficient process to implement the National Registration Scheme (NRS). The result was deemed positive at the time... "*This, combined with the emphasis on rapid science-based risk assessment by APVMA, created substantial benefits for companies, making market access easier and speeding up innovation.*".

More recent changes to the regulatory framework and its processes are perceived by member companies to have diminished these benefits, and in many cases market access is believed to be more difficult and innovation discouraged compared with other similar and competitive markets.

The Business Decisions Ltd study reported that the current regulatory environment increases both the time and cost of product development, elevates levels of uncertainty, and re-directs resources away from innovation. The effects of this are significant given the domestic R&D expenditures of animal health companies exceed A$50 million.

Significant insights into the Australian regulatory environment were gained through the member interview process and interviews with New Zealand regulatory personnel.

A measure of stagnation in the regulatory process was obtained through a survey of the majority of members companies in the Alliance. Qualified and experienced professionals within these organisations were asked to quantify the degree of delay (beyond reasonable expectations, based on science and data) in bringing innovative products to market. They were also asked to indicate the number of innovative products (available elsewhere) that could benefit Australian farmers but were not contemplated for launch due to regulatory barriers. Results were aggregated and rated to maintain commercial confidentiality issues.

Products Delayed (Production Animal only)

- *Over the last 4 years some 19 products of significant innovation (scaled 1-10) were delayed due to new difficulties in the regulatory process.*
- *The average delay period was 28 months over what would have been deemed reasonable by the regulatory professionals.*
- *APVMA issues concerning chemistry, safety or efficacy were evident in 11 cases.*
- *Delayed AQIS clearances were evident in 8 cases.*
- *APVMA trade issues delayed 3 cases.*

Products Available Elsewhere but not in Australia (Production Animals Only)

- *Some 20 major products of significant innovation (scaled 1-10) are available in other, competitive markets but are not contemplated for launch due to costs and idiosyncrasies in the Australian regulatory process.*
- *Some 17 products were relevant to the Beef and Dairy industries.*
- *5 products would be of significant benefit to the Pig and Poultry industries.*
- *AQIS policies on TSE and vaccines are preventing the introduction of at least 12 products.*
- *4 products have issues with regards the APVMA position on local efficacy or trade.*
- *Another 4 products relate to APVMA/NH&MRC positions on antibiotics.*

In every case these products are available in similar, competitive markets, often for many years. This is particularly the case for the New Zealand market where the regulatory environment allows farmers better access to innovative products. Many of the Alliance members operate in both markets.

Executive interviews conducted with the industry and regulatory officials in New Zealand illustrated the following:

1. The level of cooperation and more importantly, coordination, between the various stakeholders is high. This includes NZFSA, ERMA, Animal Health companies, processors and producers.

2. NZFSA has a strong risk management focus. It is able to address the major issues via policy and manages the minor risks by exception. The major policy and minor risk management processes are largely science and statistics based.

3. NZFSA readily accepts internationally recognised standards, such as Codex.

4. NZFSA readily accepts existing efficacy, safety and residue data, all other things being equal.

5. The New Zealand regulatory system appears to control risk at many points in the production and processing chain. Trade risk accountability is spread, as opposed to being focussed on the registration process.

1. Background

Diseases of production animals cause major economic loss to Australian agriculture. Such diseases in beef cattle, dairy cattle, sheep, swine and poultry are usually controlled by the provision of nutritional supplements and/or the application of medicinal or biological agents to either prevent or alleviate the condition. Producers rely upon scientific advances to provide timely and cost effective solutions for the treatment of diseases and conditions, allowing downstream industries involved in the production of food and fibre to compete effectively in both domestic and international markets.

The animal production industry in Australia is fragmented. Whilst the beef and sheep production sectors share some similarities in their producer base (diseases and centralised marketing of outputs, eg: red meat/Meat and Livestock Australia); the swine, poultry and dairy sectors represent a stronger degree of differentiation. As a consequence, there is little commonality in the disease importance profile, and even less in the understanding of the economic effects of these diseases. Many of the representative industry organisations and associated research bodies have not holistically quantified the economic effects of disease as most funding has been directed at marketing, production efficiency or the minimisation of a specific disease threat. An exception has been a 2006 study commissioned by MLA and Australian Wool Innovation and conducted by Sackett, Holmes et al. This report is a thorough assessment of the costs and losses associated with diseases in the Beef and Wool industry

The disease landscape is ever changing. Therefore any restriction or delay in the availability of modern animal health solutions will result in an economic impact for producers, as well as the competitiveness of downstream processing industries. This is especially true when such solutions are available in competitor countries, but are either not available or suffer delayed entry in the domestic market.

Animal health companies and regulatory authorities have therefore had to make many decisions on funding, priorities, resources and desired outcomes with no encompassing view of the economics of disease in production industries. Such an understanding becomes critically important in light of the tightly controlled and conservative regulatory environment in Australia.

The Australian regulatory environment is characterised by aversion to risk. This is understandably driven by the desire to minimise the threat from many exotic diseases or pests that are either not present in this country, or are adequately controlled. The consequences of failure are considered to include effects on trade, public safety, production and reputation. The major bodies that influence the regulatory and registration process include the APVMA (efficacy, chemistry, toxicology/residues, OH&S, registration and trade – directly or through federal or state bodies), NH&MRC (anti microbial resistance, public health), Biosecurity Australia (policy level disease and pest risk), AQIS (import risk). Other expert groups or interested parties are also often invited to give input regarding registration decision making although lack of transparency inhibits the ability to gauge their level of influence.

A particular source of complexity appears to the close association of trade issues with the regulatory process. The de facto regulation of trade compliance at the point of product registration presents risks, costs and challenges to animal health companies that are not necessarily science based. Many Australian animal health firms struggle with this additional scope of activity, as well as question the efficiency and appropriateness of such controls.

2. Objectives

Animal Health Alliance (Australia) Ltd, ("the Alliance"), representing the majority of animal health companies present in the Australian market (by $ sales), wished to more fully explore and understand the costs to Australian industry of major production animal diseases, as well as the additional costs incurred or opportunities foregone due to the absence or delayed entry of veterinary medicines/biological available elsewhere.

Menari Business Solutions (MBS) was commissioned to conduct a study evaluating the cost of disease in the Australian production animal industries. The major objective of the study was to fully analyse the costs associated in treating the major diseases of the beef, sheep, swine, poultry and dairy industries as well as understanding the associated production loss to farmers and producers when such diseases occur.

The diseases/conditions considered were those identified as being –

- Optimally treated and of economic importance;
- Sub optimally treated and of economic importance;
- Currently subject to obligatory compliance treatment;
- Untreated but of present or future economic importance.

In light of this quantification, MBS was also asked to evaluate the current regulatory environment so as to understand the gaps and opportunities that exist in the products available to Australian farmers, particularly with respect to similar competitive markets such as New Zealand.

3. Methodology

The study was conducted utilising existing data sources gained through extensive literature searches, recalibrated and updated where necessary. Where no data source existed in the literature, expert co-operators were sought who were asked to provide specific analyses regarding losses through various diseases.

Various industries differ in the focus they have on disease or condition. The beef and sheep industries clearly target diseases in their research programs and are therefore easily measured and validated using common and consistent data. Other industries focus their research efforts on conditions, with the groupings largely driven by economics. Examples of this are pneumonia and scours in swine; or reproduction and lameness in dairy cattle. Where losses and costs attributable to a condition arising from a disease or group of diseases have proven to be more quantifiable, then that condition is included.

Basic disease models for each industry were constructed using data available from existing studies, industry bodies and literature searches. Where necessary, expert co-operators were then asked to provide input to each model to quantify costs, losses and incidence. In instances where a number of data sources were used these co-operators were asked to verify the validity and accuracy of estimates and assumptions.

Loss of production can often be attributable to nutritional, environmental or other non- disease causes. Losses estimated by Sackett et al in the beef and sheep industry but not included in this study include those from

under nutrition (beef), heat stress (beef), post weaning mortality (sheep), various grass toxicities (sheep), peri-natal mortality (sheep). Similarly the losses to replacement chicks in broiler operations were also excluded due to the uncertainty associated with distinguishing between management and disease.

Infrequent or irregular catastrophic losses, especially in intensive industries, have also been excluded. This is of particular significance to the swine industry as the prevention of such outbreaks is the focus of considerable resources allocated to both the veterinary and piggery management sectors. Many of the solutions to preventing such catastrophic events are found in various management innovations

Reduced income includes losses from both clinical and sub clinical manifestations of disease. Reductions are estimates based on current disease incidence and therefore allow for situations of minimal or no disease prevention. Increased expenses include both preventative and corrective treatment, and where possible, associated costs such as labour and direct/specific preventative management. Totals are derived from the mixed environment whereby animals are given a range of measures to prevent disease, a range of therapies to treat disease once encountered, and suffer production losses that vary according to the type of treatment they receive, if at all.

MBS also extensively interviewed research and regulatory staff in the majority of Australian animal health firms, as well as representatives of industry bodies, research organisations and experts in private consultancy. To gain some perspective with regards the Australian regulatory environment, key staff from the New Zealand Food Safety Authority and Agcarm (NZ), were also personally interviewed.

Members of the Animal Health Alliance were also surveyed in order to understand the effect of regulatory delays or barriers to the introduction of innovative products to the Australian market. Measures of innovation (1=generic copy to 10=new and innovative chemistry) were given as guidelines to classify products, and experienced personnel were asked to estimate reasonable timelines based on experience, risk and overseas standards.

Products were screened and those with low levels of innovation were excluded. As a guide those ranked 4 and above provided innovation ranging from delivery mechanisms and combined therapies (at the lowest level), to new and important indications (mid level), through to new chemistry and species (at the highest).

The survey was not conducted as an audit. It was a large sample (eight firms) consisting of the majority of major animal health companies in Australia. No attempt has been made to extrapolate, therefore all figures should be viewed as minimum actuals.

4. Results and Discussion

4.1 Beef Cattle

The beef cattle industry has three different production systems that are relevant from a disease perspective. Diseases/conditions such as cattle tick, tick fever and buffalo fly are significant contributors to loss in northern (sub tropical) systems; whereas bloat, gastro intestinal parasites and pinkeye prevail in southern (temperate) systems. A major cost to feedlot systems is the control of and losses from bovine respiratory disease. Many northern herds and some southern herds are at risk from bovine ephemeral fever.

Table 2 - Beef Cattle: Costs and expenses per annum by disease/condition

	Reduced Income	Increased Expenses	Total
Disease/Condition	$	$	$
Bloat	32,178,200	16,418,910	48,597,110
Gastro Intestinal Parasites	28,107,193	11,370,213	39,477,406
Pink Eye	19,495,482	3,725,546	23,221,028
Grass Tetany	969,407	10,553,466	13,522,873
Cattle Tick	44,019,065	99,776,546	143,795,611
Bovine Ephemeral Fever	64,319,058	35,732,810	100,051,868
Buffalo Fly	65,147,215	11,885,146	77,032,361
Tick Fever	928,199	6,749,590	25,677,789
Bovine Respiratory Disease	28,647,120	8,557,150	37,204,270
Total Beef	**$303,810,939**	**$204,769,377**	**$508,580,316**

Beef cattle data were largely sourced from a recent (April 2006) study commissioned by the Meat and Livestock Association, in association Australian Wool Innovation Ltd (Sackett et al). Data sets arising from the 2001 census were recalibrated at 2007 levels. Conditions arising from non disease sources were excluded.

4.2 Sheep

The sheep industry continues to suffer significant losses from both gastro intestinal and external parasites. The rapid development of resistance in the parasite population, coupled with the "niche" status of sheep products in major product development programs of research based companies, means that products quickly suffer reductions in efficacy and are not easily replaced. Of particular note is the large in balance between reduced income and treatment/prevention (increased expenses) for gastro intestinal parasites. No doubt anthelmintic resistance issues will have a significant effect on control strategies, as will the excessive demographic "tail" of sheep producers. Clearly this area provides one of the greatest opportunities to increase industry returns using pharmacological and management solutions. The aggregation of fly strike conditions presents a different challenge, that being to minimize preventative management expenses.

Table 3 – Sheep: Costs and expenses per annum by disease/condition

	Reduced Income	Increased Expenses	Total
Disease/Condition	$	$	$
Gastro Intestinal Parasites	242,894,560	46,117,189	289,011,749
Body Fly Strike	23,258,349	57,675,043	80,933,392
Breech Fly Strike	19,932,656	95,087,613	115,020,269
Pizzle Fly Strike	21,571,667	1,831,547	23,403,214
Lice	30,509,564	65,534,521	96,044,085
Bacterial Enteritis	18,203,797	4,878,460	23,082,257
Arthritis	20,321,796		20,321,796
Footrot	3,973,367	104,652,210	108,625,577
Ovine Johnes Disease	2,009,420	1,444,744	3,454,164
Total Sheep	**$383,988,808**	**$377,221,327**	**$761,210,135**

Sheep data were largely sourced from a recent (April 2006) study commissioned by the Meat and Livestock Association, in association Australian Wool Innovation Ltd (Sackett et al). Data sets arising from the 2001 census were recalibrated at 2007 levels. Conditions arising from nutrition related causes were excluded.

4.3 Dairy Cattle

Dairy production in Australia has largely been concentrated in the south eastern temperate zone over the last 20 years and as a consequence most of the disease profile has been standardised. This is illustrated by the decline in sub tropical herds as a proportion of national milk production, thereby minimizing the role of cattle tick and buffalo fly in production loss. Whilst dairy cattle will suffer similar health issues to beef herds under like conditions, the key contributors to loss in dairy systems are those associated with mastitis, lameness and reproduction. A number of factors can contribute to these conditions and as such the industry tends to measure and treat these conditions rather than the specific disease. The Count Down Downunder program is a joint funded (Dairy Australia, State Departments of Primary Industry/Agriculture) to improve mastitis control and minimize associated loss. Significant data has been collected over the last 10 years to measure losses associated with mastitis.

Table 4 – Dairy Cattle: Costs and expenses per annum by disease/condition

	Reduced Income	**Increased Expenses**	**Total**
Disease/Condition	$	$	$
Mastitis Clinical	102,821,000		102,821,000
Mastitis Cell Counts	37,950,000		37,950,000
Mortality- Metabolic and Disease	35,920,000		35,920,000
Disease Treatment and Prevention		98,780,000	98,780,000
Total Dairy	**$176,691,000**	**$98,780,000**	**$275,471,000**

Dairy cattle data were not available from the industry body or from any centralised study. Indicative data was gained from health professionals within the industry. Specific mastitis information was sourced from the Count Down Downunder program. Mastitis cell counts were used as a measure of sub clinical loss. General disease treatment and prevention was aggregated under general veterinary costs. ABS data from 2007 was used to calibrate.

4.4 Layer Poultry

The layer industry is characterised by intensive production, significant potential for disease outbreak and therefore high costs in prevention. This is due to the longer lifespan of the layer, a high incidence (80%) of intensive cage production and some specific diseases of increased relevance to layers production (Egg Drop Syndrome). Production systems are similar across the industry. Considerable research appears to be targeted at the prevention (or worst case, control) of outbreaks of exotic diseases. Endemic disease is well controlled through a combination of prevention and treatment.

Table 5 – Layer Poultry: Costs and expenses per annum by disease/condition

	Reduced Income	Increased Expenses	Total
Disease/Condition	$	$	$
Coccidiosis	97,500	600,000	697,500
Necrotic Enteritis	16,800	900,000	916,800
Fowl Pox	96,000	1,200,000	1,296,000
Mareks Disease	720,000	2,400,000	3,120,000
Infectious Bronchitis	1,200,000	1,800,000	3,000,000
Newcastle Disease		3,000,000	3,000,000
ILT		840,000	840,000
Egg Drop Syndrome (EDS)	1,440,000	1,200,000	2,640,000
Mycoplasma	612,000	2,400,000	3,012,000
Infectious Coryza	294,000	2,880,000	3,174,000
Fowl Cholera	1,386,000	2,880,000	4,266,000
Spotty Liver	2,070,000	900,000	2,970,000
Salmonella	1,260,000	4,800,000	6,060,000
Total Layer	**$9,192,300**	**$25,800,000**	**$34,992,300**

Layer poultry data were not available from the industry body or from any centralised study. Indicative data was gained from health professionals within the industry. Disease prevention, incidence, treatment and loss data were compiled by industry co-operators and validated by cross referencing. Costs and losses were separated for both barn and cage production systems. ABS data from 2007 was used to validate. Catastrophic event data were excluded.

4.5 Broiler Poultry

The broiler industry is characterised by the production of large volumes of relatively short lived birds by highly concentrated industry operators under shed conditions. The emphasis is on prevention of disease and whilst major disease outbreaks are rare, the effect is generally catastrophic in nature. Production systems are highly similar across industry. Again, control of potential outbreaks of exotic disease is high on the research agenda.

Table 6 – Broiler Poultry: Costs and expenses per annum by disease/condition

	Reduced Income	Increased Expenses	Total
Disease/Condition	$	$	$
Coccidiosis		16,422,800	16,422,800
Mareks Disease		16,422,800	16,422,800
Fowl Pox		8,211,400	8,211,400
Infectious Bronchitis		12,317,100	12,317,100
Newcastle Disease		20,528,500	20,528,500
Total Broiler		**$73,902,600**	**$73,902,600**

Broiler Poultry data were not available from the industry body or from any centralised study. Indeed this industry had the least amount of information available, due to the concentration of production and consequent confidentiality issues. Industry co-operator information was used to estimate disease treatment costs. Losses were not estimated as overall mortality in this industry is low (adequate disease prevention and short animal lifespan), and mortality is often attributable to environmental/management causes. Catastrophic event data were excluded.

4.6 Swine

The swine industry, along with most other intensive industries has a significant body of research available on specific diseases and conditions but little on the overall cost. This is largely due to many of the diseases/conditions having significant management components in both their cause and eradication. Given the fact that this industry is also characterised by fragmentation of producer base as well as a high degree of variation in production systems, there is little chance of finding a typical or representative production unit. Indicative information is available from health and production professionals within the industry, usually with the caveat of "if there is an outbreak". The fact that many well managed units do not have outbreaks is often due to the low disease status and risk profile of their production system.

In the model below an overall health treatment cost was separated from agreed losses per sow by disease /condition. Specific treatment costs for leptospirosis and atrophic rhinitis were stripped out and the remainder of the table "solved" against a total treatment cost to get a measure of income loss vs increased expenses.

Table 7 – Swine: Costs and expenses per annum by disease/condition

	Reduced Income	**Increased Expenses**	**Total**
Disease/Condition	$	$	$
Mycoplasma	20,020,000		20,020,000
Pleuropneumonia	18,304,000		18,304,000
Swine Dysentery	28,600,000		28,600,000
Atrophic Rhinitis		10,420,000	10,420,000
Mange	17,160,000		17,160,000
Leptospirosis		6,512,500	6,512,500
(Health Cost)	(21,963,500)	21,963,500	
Total Pigs	**$62,120,500**	**$38,896,000**	**$101,016,500**

Swine data were not available from the industry body or from any centralised study. Indeed much of the research was focussed on individual diseases rather than overall incidence. A body of reports by Cutler et al, starting in 1985 and continuously updated through to 2001 were used extensively and recalibrated to 2007 data. Differing data sets provided by industry co-operators were used to triangulate costs and losses and allow separation of diseases within the category of respiratory diseases. The costs attributable to the different causes of swine dysentery were impossible to separate and are therefore aggregated. Catastrophic event data were excluded.

4.7 Member Regulatory Audit

Significant insights into the Australian regulatory environment were gained through the member interview process and interviews with New Zealand regulatory personnel.

The report by Business Decisions Ltd illustrated the degree of frustration experienced by member companies of the Alliance, and well as conveying sense of disappointment that the efficiencies sought through the creation of the APVMA had not eventuated or had been eroded.

The key issues raised by member companies were:

1. Delays due to underfunding, understaffing, or a failure to retain skilled and experienced staff at the APVMA. Particular emphasis was placed on recent delays in the Chemistry section, however members were strongly of the view that delays due to funding, training and staff turnover were endemic.

2. Failure in overall coordination and consistency between, and transparency of, decision making bodies such as Biosecurity Australia (BA), AQIS, APVMA and NH&MRC.

3. Reduced emphasis on science in the decision making process, in particular, the issue of TSE (Transmissible Spongiform Encephalopathies). Members believe the current nil risk approach by both BA and AQIS is unsupported by science, inconsistent with other similar markets (eg: NZ), costly to comply with, a barrier to innovation and a disincentive to maintain even older generation products in registration.

4. Continued reluctance to recognise international data. Whilst the members continue to support local efficacy, safety and residue studies when appropriate, it appears that the regulatory process has made little progress in recognising offshore data when the risk is low.

5. Trade compliance at point of regulation. Australia continues to minimise much of its trade risk at the product registration level through ensuring that products export slaughter intervals (ESI) comply with overseas market requirements. Unfortunately a nil risk philosophy ensures that Australian animal health companies also incur significant costs and delays preparing their products for registration, particularly for minor use markets. More pragmatic and practical solutions related to mitigation of risk, product segregation, harmonization with Codex and LoD/LoM are generally not considered. The result at best is increased costs to companies, often a product withdrawal, and worst case from an Australian producers' perspective, a termination of vital research programmes.

A measure of stagnation in the regulatory process was obtained through a survey of the majority on members companies in the Alliance. Qualified and experienced professionals within these organisations were asked to quantify the degree of delay (beyond reasonable expectations, based on science and data) in bringing innovative products to market. They were also asked to indicate the number of innovative products (available elsewhere) that could benefit Australian farmers but were not contemplated for launch due to regulatory barriers. Results were aggregated and rated to maintain commercial confidentiality issues.

Products Delayed (Production Animal only)

- *Over the last 4 years some 19 products of significant innovation (scaled 1-10) were delayed due to new difficulties in the regulatory process.*
- *The average delay period was 28 months over what would have been deemed reasonable by the regulatory professionals.*
- *APVMA issues concerning chemistry, safety or efficacy were evident in 11 cases.*
- *Delayed AQIS clearances were evident in 8 cases.*
- *APVMA trade issues delayed 3 cases.*

Products Available Elsewhere but not in Australia (Production Animals Only)

- *Some 20 major products of significant innovation (scaled 1-10) are available in other, competitive markets but are not contemplated for launch due to costs and idiosyncrasies in the Australian regulatory process.*
- *Some 17 products were relevant to the Beef and Dairy industries.*
- *5 products would be of significant benefit to the pig and poultry industries.*
- *AQIS policies on TSE and vaccines are preventing the introduction of at least 12 products.*
- *4 products have issues with regards the APVMA position on local efficacy or trade.*

- *Another 4 relate to APVMA/NH&MRC positions on antibiotics.*

In every case these products are available in similar, competitive markets, often for many years. This is particularly the case for the New Zealand market where the regulatory environment allows farmers better access to innovative products. Many of the Alliance members operate in both markets.

4.8 New Zealand Regulatory Evaluation

Feedback from Alliance member companies illustrated significant differences in the regulatory outcomes in New Zealand compared to Australia.

The New Zealand animal production industry is one of the most export oriented in the world. Its products compete strongly in overseas markets with Australian beef, lamb, dairy and wool and it generally enjoys similar benefits to Australia with regards to its disease and pest free status.

Most Alliance members quoted the comparative smoothness and transparency that they experienced in the New Zealand regulatory process, clearly evidenced by the greater range of new and innovative products available for New Zealand producers.

A strong point of difference between Australia and New Zealand is illustrated by the approach to TSE/BSE. The NZFSA recognises assessments made, among others, by bodies such as the OIE (World Organisation for Animal Health) through its Terrestrial Animal Health Code. Such assessments allow many advanced biological products to be marketed in New Zealand, products that are not allowed into Australia due to local provisions.

Executive interviews conducted with Alliance members in Australia and industry and regulatory officials in New Zealand illustrated the following:

1. The level of co-operation and more importantly, co-ordination, between the various stakeholders is high. This includes NZFSA, ERMA, Animal Health companies, processors and producers.

2. NZFSA has a strong risk management focus. It is able to address the major issues via policy and manages the minor risks by exception. The major policy and minor risk management processes are largely science and statistics based.

3. NZFSA readily accepts internationally recognised standards, such as Codex.

4. NZFSA accepts existing efficacy, safety and residue data, all other things being equal.

The New Zealand regulatory system appears to control risk at many points in the production and processing chain. Trade risk accountability is spread, as opposed to being focussed on the registration process. Other risks are recognised as manageable and are addressed using a multilayered approach.

Bibliography

ABARE (2007) – *Commodity Statistics 2007* – Australian Bureau of Agricultural and Resource Economics

ABS (2001) – *Principal Agricultural Commodities Australia 2000-2001* – Agricultural Commodities Australia, Australian Bureau of Statistics, July 2002

ABS (2008) – *Principal Agricultural Commodities Australia 2007-2008* – Preliminary Report: Agricultural Commodities Australia, Australian Bureau of Statistics, Nov 2008

Business Decisions Ltd (2007) – *Benchmarking the Competitiveness of the Australian Animal Health Industry* – Report: Animal Health Alliance, International Federation for Animal Health

CSIRO (2004) – *Breeding Mastitis out of the Dairy Herd* – Media Release

Cutler R (1987) - *The Cost of Pneumonia in Pigs* – Notes: Victorian Dept of Agriculture and Rural Affairs

Cutler R, Gardner I (1988) – *A Blue Print for Pig Health Research* – Paper: Victorian Dept of Agriculture and Rural Affairs

Cutler R et al (2001) – *Eradicating Diseases of Pigs* – Publication: Pig Research and Development Corporation

Halligan R (2008) – *Recent Changes to AQIS Vaccine Import Assessment Procedures* – Industry Presentation to VVSC: Intervet Schering Plough

Moir D (2003) – *Biosecurity in the Pig Industry* – Notes: WA Dept Agriculture Farmnotes 46/2003

Page S (2003) – *The role of enteric antibiotics in livestock production* – Review: Avcare Ltd May 2003

Parke K (2004) – *Pig Diseases Guide* – Notes: DPI&F Pig Technotes Dec 2004

Parke K (2004) – *Routines for Pig Disease Prevention* – Notes: DPI&F Pig Technotes Dec 2004

Parke K (2004) – *Sarcoptic Mange in Pigs* – Notes: DPI&F Pig Technotes Nov 2004

Pointon A (1994) – *Pleuropneumonia Workshop Adelaide* – Paper: Pig Research and Development Corporation

PoultryHub (2008) – *Chicken Layer Industry* – Website notes: www.poultryhub.org, Poultry Cooperative Research Centre

PoultryHub (2008) – *Chicken Meat (Broiler) Industry* – Website notes: www.poultryhub.org, Poultry Cooperative Research Centre

PoultryHub (2008) – *Poultry Health Management* – Website notes: www.poultryhub.org, Poultry Cooperative Research Centre

Sackett D, Holmes P, Abbott K, Jephcott S, Barber M (2006) – *Assessing the economic cost of endemic disease on the profitability of Australian beef cattle and sheep producers* – Report: Meat and Livestock Australia Ltd

Skirrow S, Cargill C, Holyoake P, Cutler R (1995) – *Pleuropneumonia: A blueprint for diagnosis, control and prevention of pleuropneumonia caused by Actinobacillus pleuropneumoniae* – Paper: Pig Research and Development Corporation

WA Dept of Agriculture (2001) – *Strategic Assessment: Endemic Diseases in Pigs* – Notes: Stockyard Pigs series December 2001, WA Dept of Agriculture

WA Dept of Agriculture (2002) – *Strategic Assessment: Endemic Diseases in the Avian Industries* – Notes: Stockyard Avian series July 2002, WA Dept of Agriculture

5. Appendices

6.1 Interviews Conducted (number)

Agcarm – Graeme Peters (1), Jan Quay (1)

Australian Farm Institute – Michael Keogh (2)

Bayer Australia Ltd – Neil Cooper (2)

Boehringer Ingelheim Pty Ltd – Ian Douglas (2), Jillian Walker (2)

Elanco Animal Health – Lisa Wade (2), Kim Agnew (1), Darryl Meaney (1)

Fort Dodge Australia Ltd – David Chudleigh (2)

Intervet Schering Plough – Rebecca Halligan (3), Mark Albrecht (1)

Meat and Livestock Australia Ltd – Michael Goldberg (1)

New Zealand Food Safety Authority – Debbie Morris (1), Warren Hughes (1)

Novartis Animal Health Australasia Pty Ltd – Stephen Neutze (1), Harry Collins (1)

Pfizer Animal Health – Mike Van Blommestein (3), Domenic Dell'Osa (2), Les Cooper (2), Ross Henderson (1)

Virbac (Australia) Pty Ltd – Paul Martin (2)

6.2 Industry Sources and Co-operators

Australian Chicken Meat Federation – Vivian Kite

Australian Egg Corporation – James Kellaway

Australian Pork Ltd – Darryl De Souza, Patricia Mitchell, Andrew Spencer

Australian Poultry CRC – Mingan Choct

Countdown Down Under Program – John Craven

Dairy Australia Ltd – Helen Dornom, Sandy McKendrick

Golden Cockerel Pty Ltd – Rod Jenner

IAS Management Services/ UQ – Kit Parke

Pork Journal – Peter Bedwell

Ross Cutler and Assoc – Ross Cutler

Scolexia Pty Ltd – Peter Scott

6.3 Advice from NZFSA regarding BSE and SPF Eggs

<Email communication 2nd Oct 2008 (Reproduction permission granted)>

John - we have followed up on the queries you raised in the meeting with Warren and me.

1. Eggs / Vaccines - we know it is a general requirement to use SPF eggs but we have no knowledge of why this would be limited to SPF from a specific country and there are no requirements over and above the general ones in relation to New Zealand

2. BSE / Milk - Trish talked to our New Zealand expert (who is also one of the international leading lights in this area) and his advice was as follows:

Milk and milk products pose no BSE risk. See the following clip from the 2008 Terrestrial Animal Health Code:

Article 11.6.1. General provisions and safe commodities

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Authorities* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*:

a) *milk* and *milk products*;

b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

c) hides and skins;

d) gelatine and collagen prepared exclusively from hides and skins;

e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

f) dicalcium phosphate (with no trace of protein or fat);

g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, which were not subjected to a stunning process prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante-mortem and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.6.14.;

h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

Hope this answers your queries

Regards
Debbie Morris
Director (Approvals and ACVM)
New Zealand Food Safety Authority

6.4 Listing by member company (blind) of delayed or absent products

Company	Delayed - Number of Products			Not Available - Number of Products		
	Innovation Ranking			Innovation Ranking		
	(4-5)	(6-7)	(8-10)	(4-5)	(6-7)	(8-10)
A	3	2			2	
B	1					2
C	3			1		
D			1		1	1
E	1		2	1		7
F	1					
G		1	1	4		1
H	1	1	1			
Total	**10**	**4**	**5**	**6**	**3**	**11**

6.5 Listing by type of delayed and absent products

Product Type	Delayed - Number of Products			Not Available - Number of Products		
	Innovation Ranking			Innovation Ranking		
	(4-5)	(6-7)	(8-10)	(4-5)	(6-7)	(8-10)
Anti-Coccidials	2		1			
Anthelmintics	3	1				
Other Vaccines and Antibiotics	3	2	3			
Ecto Parasiticides	2	1	1			
Vaccines				4	3	7
Antibiotics				2		3
Other						1
Total	**10**	**4**	**5**	**6**	**3**	**11**

6.6 Listing by species of delayed or absent products*

Species	Products Delayed				Products Unavailable			
	Innovation Ranking				Innovation Ranking			
	(4-5)	(6-7)	(8-10)	Tot	(4-5)	(6-7)	(8-10)	Tot
Beef**	2	2	2	**8**	4	1	10	**15**
Sheep	3	1	1	**5**				
Dairy**	1	1		**2**	2		2	**4**
Swine	1		1	**2**			2	**2**
Poultry	4	1	2	**7**	1	2	2	**5**

*Products may have more than one species application

**Many beef products will have common application in dairy but are not recorded as such

ATTACHMENT 2

Errors/inconsistencies in the Agvet Chemical draft exposure Bill

Exposure Draft, **Schedule 1, Decision-making using a risk based framework**; page 14; item 57 referring to **section 56ZU (4) (c) (iv) and (v)** of the schedule; the exposure draft indicates amendments to parts **(4) (c) (iv) and (v)** yet the supplied mocked up version of the **Code Act** (page 173) has the proposed additional wording (**if the APVMA considers it relevant**) inserted in **part (4) (c) (i) and (ii)** instead of the proposed **part (4) (c) (iv) and (v)**.

Part 10 – Miscellaneous, page 356 **(section 165)** and page 358 **(section 166)** of the mocked up version of the **Code Act**, have an inconsistency in that insertion of the proposed wording under "**2-32** ". The exposure draft indicates that "**2-32**" relates to **section 166** yet "**2-32**" is duplicated in the exposure draft on page 356 in **section 165** but with different amendments.

Significant alignment errors occur on pages 3 and 4 of the mocked up version of the **Administration Act** in respect to "**4-17**" through to "**4-24**". This misalignment appears in viewing and printing both the word and the PDF versions. Similar problems occur on pages 88, 89, 90, 94 and 96 of the mocked up version **Administration Act** relating to "**4-44**"; "**4-45**"; "**4-46**"; "**4-47**"; "**4-48**" and "**4-49**".

Exposure Draft, **Schedule 4, Enforcement**; page 134; **item 147** referring to **subsection 112 (2)** of "**Permit Part 7**" page 244 of the mocked up version of the **Code Act** has the numbers "**4-147**" missing from the document.

Exposure Draft, Schedule 6, Arrangements for collecting levy page 203; **item 1** referring to **Subsection 3 (1)** page 1 of the mocked up version of the **Collection Levy Act** has the numbers "**6-1**" missing from the document.

SUBMISSION - ATTACHMENT 5.

Animal Health Alliance
SOLUTIONS FOR THE FUTURE

Animal Health Alliance (Australia) Ltd
ABN: 76 116 948 344
Address: Level 2 AMP Building
1 Hobart Place
Canberra ACT 2601
Locked Bag 916
Phone: 02 6257 9022
Fax: 02 6257 9055
www.animalhealthalliance.org.au

19 October 2012

Agvet Chemicals (Better Regulation Reforms)
Agricultural Productivity Division
Department of Agriculture, Fisheries and Forestry
GPO Box 858
Canberra ACT 2601

Agricultural and Veterinary Chemicals Legislation Amendments Bill 2012 Revised Exposure Draft September 2012 – Animal Health Alliance (Australia) Ltd Submission

The Animal Health Alliance (Australia) Ltd (the Alliance) is the voice of the animal health industry in Australia. It represents registrants, manufacturers and formulators of animal health products. The association's member companies represent in excess of 85 per cent of all animal health product sales in Australia (ex-factory gate). The Alliance manages both national and state issues with the objective of ensuring its members can operate within a viable regulatory environment. The Alliance also contributes to sustainable industry risk reduction practices that provide business opportunities to members and add value to the broader Australian community.

The Alliance and its member companies recognise that the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code) is the primary Act regulating veterinary chemicals and associated products in Australia and as such we have a strong interest in any proposed amendments to this Act. This is particularly so where the reform focus is to improve APVMA efficiency and performance. The objective 'to cut red tape and increase the efficiency and effectiveness of agricultural and veterinary (agvet) chemicals regulation'[1] is a common aspiration for industry and government. With this common aspiration it is unfortunate then that the Alliance remains concerned that the proposed reforms would likely fail to deliver. This Revised Exposure Draft confirms that the proposed amendments to the Agvet Code include additional functions and processes that, if implemented as proposed, will hinder APVMA efficiency and deliver no additional health, safety or environmental protection benefits to Australia. The Alliance's interpretation of the proposed amendments Bill is an increase in regulatory burden on product registrants with no tangible benefits delivered.

The consequence of increased regulatory burden without net benefit can be significant. The Alliance has recently released the International Federation for Animal Health (IFAH) Global Benchmarking Survey 2011 where the performance of veterinary chemical regulators in various OECD countries is assessed against set parameters (http://www.animalhealthalliance.org.au/default.asp?V_DOC_ID=1792). The 2011 survey results covered regulatory performance since 2006 and the APVMA has slipped over that timeframe from being equal first in the ranking to the bottom of the rankings. If the proposed regulatory amendments to the Agvet Code are not handled appropriately the

[1] http://www.daff.gov.au/media_office/media_releases/media_releases/2011/november/refprms-a-boost-for-agriculture-and-veterinary-cheimcals

Alliance is concerned that APVMA will still find it extremely difficult to address the performance issues that have seen it fall so precipitously when compared to regulators in other markets.

Appropriate regulation of veterinary chemicals and associated products is critical for instilling community confidence relating to food safety/quality and environmental protection. For regulation to be appropriate, it needs to allow for community and consumer protection through risk management and facilitate access to animal health innovation. Inappropriate and/or ineffective/inefficient regulation adds nothing to community confidence and only exacerbates existing regulatory problems undermining confidence in the regulatory process and negatively impacting on future research and development investment (see IFAH Benchmarking Survey 2011). The Alliance remains disappointed and concerned that the proposed amendments to the Agvet Code are unlikely to deliver on the mutually agreed aspirations for the APVMA.

The Alliance notes that a number of issues we raised in response to the first Exposure Draft in February 2012 remain unaddressed. The Alliance remains committed to our positions communicated to Government in our first submission on this amendments Bill.

The Alliance looks forward to continuing to work cooperatively with Government in identifying efficiencies in processes and creating new attitudes/approaches to risk/benefits in considering veterinary chemical product applications so as to deliver on the opportunities provided the *Better Regulation* reform process.

All Alliance comments in this submission are supplied on the understanding that the accompanying proposed regulations have only recently been released and industry will require further time to appreciate the consequences of all proposed regulatory changes.

Yours sincerely

Dr Peter Holdsworth AM FAICD
Chief Executive Officer
Animal Health Alliance (Australia) Ltd

Animal Health Alliance (Australia) Ltd

Submission to

Agricultural and Veterinary Chemicals Legislation Amendments Bill 2012 Revised Exposure Draft September 2012 – Animal Health Alliance (Australia) Ltd

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Agricultural and Veterinary Chemicals Legislation Amendments Bill 2012 Revised Exposure Draft September 2012 – Animal Health Alliance (Australia) Ltd Submission

Commencement/implementation dates

The Alliance is unconvinced so far, that the proposed implementation schedule and process for these reforms is a considered exercise. Irrespective of the commencement date, the APVMA will have in its system applications accepted and being assessed prior to the date of commencement of these amendments. The process appears to be silent on how such applications will be dealt with if the APVMA fails to complete its review in the two year period after commencement of the new code.

The Alliance seeks assurances that no member company already engaged within the APVMA system on an issue (being it an application of any type or even ongoing compliance actions) will be disadvantaged by the commencement of the new Code. This could mean that the APVMA would need for a time period to run concurrent processes with one process running to capture activities that are running and incomplete under the existing Code as of the implementation date for the new Code, and a second process running to implement the new Code and capture new activities as of the commencement date. The Alliance does understand that this approach cannot be sustained indefinitely and would support a final transition to new arrangements after a number of years of concurrent operation.

Given that the Exposure Draft indicates that the proposed new amendments would commence from 1 July 2013, practically thinking, this would appear an unrealistic timeframe. These proposed amendments encompass significant changes in process and operation not just for the APVMA but also for product applicants and registrants. At this point in time the proposed accompanying regulations have not been completed and a draft of these is out for stakeholder consultation until 21 December 2012. The proposed amendments Bill has not even at this stage been passed by Parliament. Recognition needs to be given to the impediments this Bill will impose on product applicants and registrants in learning the required new processes and procedures. This includes careful consideration of what information will be required to meet the legislative tests applied by the APVMA. The Alliance members are currently preparing applications for submission to the APVMA over the next 2-3 years. If these amendments commence from 1 July 2013 as currently proposed, then applicants will be faced with uncertainty as to what will be the APVMA new application requirements. The Alliance has strongly advocated for the preparation and completion of the risk framework well in advance of any commencement date for the amendments Bill.

If the objective of the risk framework is to enable quality applications to be made, then this risk framework describing how applicants are to meet the safety, efficacy and trade criteria needs to be completed, prior to the implementation date for the amendments Bill. At the same time that the risk framework is released an education program will need to be implemented so stakeholders are appropriately informed.

Based on this practical reality, the Alliance strongly recommends delaying implementation of these measures at least until the risk framework can be developed in full consultation with all affected stakeholders. From a cost/benefit or risk/benefit perspective it is logical to have all the necessary supporting documentation in place prior to the implementation date.

The present cost and benefit analysis that underpinned the amendments Bill was, in the Alliance's view, largely subjective, inaccurate and reliant on a series of presumptions about the legislated reforms that are out dated. Without an up-to-date and persuasive analysis to indicate that the significant costs associated with these reforms will deliver genuine health and environmental benefits, the Alliance cannot support the package.

Indeed the expected costs associated with implementation of these reforms are a significant cause for concern for the Alliance members. The Cost Recovery Discussion paper released in December 2011 highlighted that the ongoing increase in regulatory cost is expected to be at least $2.8m each year. This includes $0.85million for enhanced compliance activities and $1.95million to support operation of the re-registration scheme[2]. The Alliance had understood that the cost recovery proposed in this discussion paper would not be applied until after the 'First Principles' cost recovery process had been concluded; The Alliance now notes that the application fees proposed in the Discussion Paper appear in the draft regulations released with this draft amendments Bill.

Until the precise nature of the ultimate package of reforms are finalised and the appropriate government response to cost recovery for the APVMA is determined, the level of fees and levies to be applied to APVMA functions should not be set.

Hazard versus Risk

The APVMA is a risk based decision maker in relation to the legal supply, possession, use and disposal of veterinary chemical products. Risk based registration systems offer product users appropriate management advice relating to the most important hazards associated with the product, through clear label instructions. The Alliance continues to support risk management as the primary tool for regulating veterinary active constituents and their associated products in Australia.

The Alliance does not support approaches to regulation of veterinary chemical products that focus solely on the hazards associated with the active constituents in the products.

The Alliance is concerned that elements of hazard control are appearing in the Agvet Code and its subordinate regulations and are being intermingled with risk control statements (see sections 5A (1) (a); 34K (3) and (4a); 34N (4); 35 A and 47A (1) (b) (i)). While this does appear to be limited to calculation of timeframes for re-approval and re-registration, the precedent that this establishes moves Australia's system for regulating veterinary chemical products further away from best practice.

Review of Operation of Amendments

The Alliance acknowledges that section 4 requires the Minister to conduct a review of the proposed amendments within 5 years of commencement. This requirement should not preclude a full assessment of the impact of these proposed amendments in advance of the initial implementation date.

The Alliance is yet to be convinced that the cost imposts flowing from the amendments Bill will be outweighed by any efficiency or productivity benefits from the reform package. This appears to be confirmed by cost recovery documents that indicate significant increases in the level of cost recovery sought from applicants and registrants as well as the introduction of significant new APVMA processes and functions.

To incorporate any additional functions to APVMAs existing processes, these functions must be assessed on a cost/benefit basis in relation to delivering a net community benefit. This should occur prior to the commencement date of this amendments Bill.

The Alliance remains unconvinced that there will be any broader environmental or community benefits from these reforms. To date, no review has identified market failure with respect to the existing APVMA regulatory oversight in managing the risk to health, safety or the environment from veterinary chemical active constituents and associated products. Indeed the core issue that has been identified by a number of reviews, (including those by the Australian National Audit Office and the Productivity Commission) is that the APVMA is inefficient in fulfilling its existing functions.

[2] APVMA Cost Recovery Discussion Paper p47

Schedule 1: Approvals, registrations, permits and licences

The Alliance welcomes reforms that seek to improve and streamline the assessment of veterinary chemical active constituents and their associated products. Many of the proposed amendments seek to update and restructure the current legislative approach; however subtle changes may have the capacity to significantly change the operation of the regulatory system.

The following comments in relation to specific provisions are offered.

Pre-application assistance

The Alliance notes the intention to provide pre-application assistance for applicants. The cost to applicants of any pre-application assistance (up to an established regulatory limit) would be recouped through a rebate on the application fee paid with the subsequent full product application. This essentially amounts to the APVMA providing assistance to applicants preparing applications at no net cost to them.

This process builds in additional inefficiency, cross-subsidisation between applicants as well as requiring the APVMA to operate as a *de facto* regulatory affairs consultant on applications. If the Government considers that it would be desirable to provide applicants with assistance in meeting regulatory requirements when preparing applications for the APVMA, this should either be:

1. Managed through a specific program and funded from general revenue, or
2. Fully cost recovered from those applicants that use the service.

1A Implementing the Code

The Alliance is concerned in relation to a new concept in the proposed new paragraph (c) that requires that the Code be implemented in a manner that reflects '*contemporary principles'* based on '*relevant science'*.

No definition has been offered to understand what '*contemporary principles'* are intended to imply. Without such a definition it is difficult to consider what impact this may have on the current APVMA regulatory system. The Alliance advocates that Government provide further information on the meaning of these two terms and how the APVMA is expected to consistently implement these.

The Alliance notes with interest the wording in paragraph (d) where the APVMA in making any regulatory decision in the future will need to implement this Code in a manner that "*balances regulatory effort and any burden imposed by the system of regulation on the domestic industry for manufacturing and formulating chemical product and their constituents……*.". For many of the Alliance member companies that are multinational in origin and formulate and manufacture product overseas for import into Australia, this paragraph raises concern or confusion. The proposed wording here specifically highlights that the APVMA has to give consideration, in any pending regulatory decision that it may be considering, to the impact of that decision on a party (presumably an applicant/registrant/licence holder) if that party is a domestic based company. Some Alliance members interpret this wording as potentially treating applicants/registrants/licence holders differently in the regulatory decision making process based on whether they are an Australian or a multinational based entity. Similarly, subject to how ultimately the application of this paragraph emerges in APVMA operating processes there will be an additional new step imposed in the regulators activities prior to taking a decision. The APVMA will need to have documented how it has satisfied the requirements of this paragraph. The Alliance seeks further clarification of the actual intent of paragraph (d) and in addition how the APVMA intends to implement it and what resource impact and delays to the registration timelines are envisaged.

The Alliance is similarly concerned by the reference to '*unmanageable risks'* referred to in paragraph (e). Ultimately, if the APVMA considers that the risks from a veterinary chemical product are unmanageable, then the APVMA already has the responsibility to not approve an active constituent or register the accompanying

product. The Alliance is concerned that the phrase '*unmanageable risk*' has been used to advocate for restrictions on chemical products even after they have been subject to a risk assessment by the APVMA and registered. Ultimately, the final arbiter of what amounts to a manageable and unmanageable risk must be the APVMA.

5A Definition of meets the safety criteria

The Alliance is concerned at the construction of the current test for meeting the safety criteria. Paragraph (1)(a) of this test requires any active constituent or product to not be '*an undue hazard to the safety of people exposed to it*'. Hazards are intrinsic qualities associated with a particular chemical, and are generally not quantifiable. An undue hazard consequently is unclear and imprecise. The Alliance recommends that the word '*hazard*' in this paragraph be replaced with the word '*risk*'. The Alliance suspects that this amendment from *'hazard'* to '*risk*' more closely reflects the intention of Government to restrict products that present an undue risk to the safety of people or the environment. A similar situation appears to exist in section 47A (1) (b) (i) however, here it is relating specifically to active constituents.

6A APVMA may make guidelines etc.

The Alliance welcomes amendments to enable the APVMA to make appropriate guidelines that are essential to providing certainty to applicants about the way that their application will be treated. The current Manual of Requirements and Guidelines has served this purpose in the past, however, it is not currently specific or detailed enough to effectively provide sufficient guidance.

APVMA guidelines must also apply to risk assessment advice sought by APVMA from external agencies. Current practices where external agencies (DSEWPAC and OCSEH) can "override" existing APVMA requirements for risk assessments undermines industry's confidence in the regulatory process. This is pivotal as a basis for consistent evaluation of risk.

11 Preliminary assessment (new approvals and registrations)

The Alliance supports provisions that seek to improve the performance of the APVMA. The proposed new section 11 seeks to achieve this by providing for a stricter process for a preliminary assessment. Currently, if the APVMA determines that an application does not contain all required information for it to pass preliminary assessment, it can delay consideration of that submission while the applicant prepares additional data or alternatively treat the application as having been withdrawn.

Under new requirements, if an application does not meet the application requirements, the application must be refused.

The Alliance has two concerns with the new system of preliminary assessment:

(1) Given that applications failing at this assessment will be refused, this completeness check needs to truly be an administrative check rather than a more detailed (technical) assessment.

(2)The new preliminary assessment process will have detrimental impacts in terms of data protection. The new definition of *protected information* under section 3 (1) is interpreted as meaning that any information that is not linked to an approved active constituent or a registered product is not protected. Consequently, should an application be refused – even if refused because of an administrative oversight on the part of the applicant – the commercial value in any data submitted with that application will be reduced.

The Alliance would recommend the inclusion of appropriate amendments to allow an applicant to reclaim data submitted with an unsuccessful application and that such data would be protected if resubmitted with a subsequent application.

While the Alliance welcomes measures that allow the APVMA to manage the application processes better, amendments that penalise applicants for APVMA failures are not supported. The Alliance is concerned that section 11(3) could operate such that if the APVMA is not able to complete a preliminary assessment within 1 month, the application must be refused. This would be an undesirable interpretation that would not be supported by the Alliance.

28 Preliminary assessment (varying relevant particulars and conditions)

Similar to comments in relation to section 11, the Alliance remains concerned about the potential loss of data protection resulting from measures to streamline application procedures. The Alliance would support appropriate amendments that allow applicants to reclaim data submitted with an unsuccessful application for variation.

31 (2) and (3) Reconsideration (requirements for APVMA to prepare a work plan)

The Alliance supports measures to facilitate a more effective reconsideration process. Requiring the APVMA to prepare and maintain a work plan may assist approval holders and registrants decide their level of engagement with any reconsideration process, and provide some certainty around that process. It will be important in this situation that the APVMA consults closely with affected registrants when developing a work plan, as a commitment to develop any necessary additional data will need to be coordinated with registrants to ensure that any proposed work plan is achievable and relevant.

The Alliance sees value in an amendment that would require the APVMA to consult with all approval holders (active constituent) and registrants of veterinary chemical product under reconsideration prior to finalising any work plan.

32 Notice of reconsideration

The Alliance supports those measures designed to improve the way that reconsideration processes are managed by the APVMA. The Alliance remains concerned however, that these reforms may not address core problems that operate as a disincentive for approval holders and registrants to participate in a reconsideration process.

While the provisions of providing notice about reconsideration are welcomed, including the requirement that the APVMA must supply details of the work plan, incentives still remain for approval holders and registrants to delay engaging in any review process.

The Alliance understands the need for the APVMA to access existing information in a timely manner. The current proposal however may impose obligations on approval holders and registrants that are both unnecessary and difficult to comply with. Requirements under section 32(1)(b) that oblige an approval holder or registrant to provide information of a kind stated in the APVMA notice may prove to be problematic. While an approval holder or registrant may be aware of information, this does not necessarily mean that they have either access to or control of that information.

The Alliance objects to an offence being created where an approval holder or registrant fails to provide information to the APVMA when that information is not within their care or control. The Alliance would suggest that it would be preferable to only require information to be provided to the APVMA when that information is within the care and control of that approval holder or registrant.

34A Varying relevant particulars

The Alliance supports the content of section 34A to require the APVMA to vary relevant particulars or conditions in situations where doing so would satisfy the APVMA that an active constituent or product meets the relevant safety, trade and efficacy criteria.

156A Giving information electronically

Measures to allow applicants, approval holders and registrants to give APVMA information electronically are welcomed. This is an overdue reform that has the potential to minimise the cost to the APVMA in handling information. Paper copies of documents should only be required where absolutely essential.

160 Overseas trials and experiments etc.

Reforms that will enable the APVMA adopt, where appropriate, decisions and evaluations made by overseas regulators are supported by the Alliance. However, some restrictions about how the APVMA may consider overseas decisions and evaluations may be appropriate. Not all regulators make decisions is ways that are comparable to Australia's risk based processes. As has occurred in other areas of these reforms, it may be beneficial to expressly specify comparable regulators that make high quality risk based decisions in a similar manner to the APVMA.

The Alliance does recognise that new section (3) (d) of the section would require the APVMA to consider differences in the way that different regulators undertake evaluations or make decisions. The Alliance supports inclusion of this additional qualification.

165A Period within which APVMA is to conclude reconsiderations

The Alliance would urge caution when considering establishing timeframes for concluding reconsiderations. While timeframes may be useful for the APVMA in establishing work plans for finalising reconsiderations, establishing timeframes without understanding the reasons why existing reconsiderations take such a long time to finalise may simply result in products that could be used safely being cancelled.

Veterinary chemical products under reconsideration are often generic products well past any patent protection period. This means that there are often a large number of approval holders and registrants for any veterinary chemical to be reconsidered. Many of these approval holders and registrants have little interest in developing data to support ongoing approval or registrations, preferring instead to leave these tasks to other registrants.

In the Alliance's experience one of the key reasons for delays in reconsideration is the significant incentive that exists for approval holders and registrants to defer making a decision about planned involvement in any reconsideration process. Unless approval holders of active constituents and registrants of products under reconsideration are compelled to declare their intention to support their product, delays will continue.

The Alliance would support defined periods for concluding reconsiderations on the provision that those approval holders and registrants that do not wish to participate in any information and data generation activities have a regulatory impost imposed on their approvals and registrations at an early stage in the reconsideration process.

Developing data is often a particularly time consuming process. In some circumstances, multi-year residue or efficacy data may be required to satisfy the APVMA that a particular active constituent or product meets the safety criteria. This could delay conclusion of the reconsideration beyond the timeframe permitted. The Alliance would suggest that where registrants have committed to a work program to develop data for consideration by the APVMA in good faith, then there should be scope for the APVMA to extend the time for conclusion to facilitate evaluation of any additional data.

Schedule 2: Re-approvals and Re-registrations

The Alliance remains concerned that proposals to introduce a scheme to re-approve active constituents and re-register products builds another layer of bureaucracy without providing any meaningful improvement in human health, safety or environmental protection. While the Alliance understands that introduction of a re-approval and re-registration scheme was part of the election commitment given prior to the 2010 election, it does not represent good policy and as such should be revised. The need for a re-approval and re-registration scheme stems from an assumption that the APVMA is currently not managing its existing chemical product portfolio properly.

Reviews by the Productivity Commission and the Australian National Audit Office have confirmed that the APVMA has reasonable arrangements for identifying and prioritising existing chemicals requiring review.

The Alliance accepts that there are current problems with excessive delays under the APVMA's Existing Chemical Review Program. However, creating an additional bureaucratic process to add additional chemical products to the existing review priority list will not help address concerns about the time taken to complete a re-consideration. It is concerning that the measures proposed in the second Exposure Draft appear not to be targeted at addressing the core problems associated with the current Chemical Review Program. Instead, creating an additional bureaucracy and inefficiency through a questionable process, there is likely to be less capacity for the APVMA to deliver timely, high quality chemical reviews.

A risk framework describing the criteria through which active constituents and products would be assessed is essential. This is particularly the case when the new section 1A introduces novel, undefined and imprecise concepts such as '*contemporary principles*', '*relevant science*' and '*unmanageable risks*'. Approval holders and registrants require certainty about the standards against which their active constituents and products will be assessed. At this stage, no such standards have been offered up.

The expected costs of a re-approval and re-registration scheme remain concerning to the Alliance and its members. The Cost Recovery Discussion Paper released by the APVMA in December 2011 confirmed that re-approvals and re-registrations would expect to cost the APVMA approximately $2million each year to administer. This does not include the costs to applicants required in preparing applications and meeting APVMA requirements which would exceed the APVMA's administrative cost. The Alliance would expect to see corresponding improvements in health, safety or environmental benefits that make this investment worthwhile. Unfortunately, there appears to be little evidence that this will be the case. Indeed, additional bureaucratic and administrative functions required by the APVMA that do not assist in managing risks from products may ultimately result in distracting the APVMA from its core business of providing risk assessments, decisions and managing the existing veterinary chemical product portfolio.

While these core concerns about the utility and efficiency impacts of the re-approval and re-registration scheme remain, the Alliance would continue to support the existing approach to identifying and prioritising chemicals for review. Ideally, improvements to the current Chemical Review Program should focus on identifying and addressing the precise reasons why reviews are excessively delayed.

Despite the Alliances' concerns about the effectiveness of the proposed re-approval and re-registration schemes, we offer the following comments in relation to specific amendments proposed in this Exposure Draft.

29D Application

This section requires that applications for re-approval and re-registration must occur between 6 and 3 months before expiry of the registration. While the Alliance understands that the regulations may make provision for applications to also be made less than 3 months before expiry, there seems to be little justification for this

restriction. The Alliance would recommend that applications for re-approval and re-registration should be able to be made less than 3 months before expiry without restriction.

The time that approval holders and registrants will require to prepare re-approval or re-registration applications will be dependent upon the application requirements. At this stage, regulations linked to section 8B which would specify the information that must accompany an application have not been prepared, and the practicality of the application procedure cannot be verified.

29E Preliminary Assessment (re-approvals and re-registrations)

The Alliance welcomes measures that allow the APVMA to better manage application processes. However, amendments that penalise applicants, approval holders and registrants for APVMA failures are not supported. The Alliance is concerned that section 29E(3) operates such that if the APVMA is not able to complete a preliminary assessment within 2 months, the application must be refused. This would be an undesirable interpretation that would not be supported by the Alliance.

Appropriate amendments that seek to ensure that where the APVMA is not able to meet its obligations under 29E(1), applicants are not disadvantaged through an unfair and inappropriate refusal of an application are required. As under section 11, the Alliance is concerned with the treatment of any commercially sensitive data that may be submitted with a re-approval or re-registration application where that application is refused.

29F Re-approval or re-registration

The Alliance notes that this section introduces a new legislative test for re-approving active constituents and re-registering products. The new test is that the APVMA must re-approve a constituent unless there are '*reasonable grounds to believe that the constituent* (or *product*) *does not meet the safety criteria'* is clearer and more specific than previous tests considered. However, the Alliance still expresses concerns that the definition of '*meets the safety criteria'* includes an unacceptable and undesirable hazard element into the assessment. The Alliance has discussed this concern above in relation to the proposed new section 5A.

The Alliance would welcome further consideration of what would amount to '*reasonable grounds*'. Greater understanding of the application of these terms will have a critical impact on the effectiveness of the re-registration and re-approval scheme. Inclusion of subjective elements of reasonableness may result in significantly increased uncertainty and regulatory risk for approval holders and registrants.

The Alliance does note that the same test is applied to all products irrespective of the hazards that their active constituents might present. As the APVMA may only re-register products where there is no reason to doubt that the product meets the safety, trade and efficacy criteria, justification for providing different re-registration time periods for products is unsubstantiated.

The proposed regulations seek to define the period for which a product or active constituent would be reconsidered through a hazard matrix. This is in contradiction of the Government's own stated policy which committed it to establishing re-approval and re-registration periods on the basis of risk.

Where active constituents and products meet the same regulatory standards they should receive the same benefits. This would mean that each active constituent and product should be re-registered and re-approved for the same timeframe. The Alliance recommends that as long as the legislative tests are met, products and active constituents should be re-registered and re-approved for 15 years.

Periods for re-approvals and re-registrations are to be determined by the regulations. The Alliance notes that it is Government's intention to specify re-approval and re-registration periods according to the risk of the active constituent or the chemical product. However, the proposed methodology outlined for proposed regulations suggests that re-approval and re-registration periods would be determined solely on the basis of their hazard.

No consideration of the potential exposure of an active constituent or a registered product is taken into account.

The Alliance considers that this approach represents an unacceptable shift away from the established risk management principle of Australia's regulatory system for chemicals management. Without a proper process based on the risk an active constituent or an associated product presents, the current process has the potential to impose greater regulatory costs on some products even in circumstances where they do not present any greater risk to health, safety or the environment.

29G Varying relevant particulars and conditions to allow re-approval or re-registration

Requiring the APVMA to consider varying relevant particulars and conditions to allow re-approval or re-registration is supported by the Alliance. This measure is consistent with existing provisions within the Agvet Code for reconsiderations and permits a level of flexibility in the way that the APVMA can administer its functions while still delivering on its legislative remit.

Allowing this activity is also likely to minimise the number of active constituents and registrations that are ultimately referred for reconsideration.

47A Varying duration— decisions of foreign regulators

Ideally, the APVMA should be free to administer its veterinary chemical product portfolio in accordance with Australia's specific circumstances. Providing an additional trigger for products to be re-registered or reconsidered on the basis of overseas regulatory decisions is unlikely to change the practical outcomes in comparison to the current approach by the APVMA.

Currently, the APVMA monitors contemporary and comparable regulators around the world to determine whether their regulatory decisions might have an impact on an Australian registered product or an approved active constituent. At any point in time, if the APVMA considers it necessary, a product or active constituent can be placed under review. The APVMA can do this if it identifies information not only resulting from a comparable regulator, but also any other source.

The Alliance supports the proposal to proscribe comparable overseas regulators. This would preclude attempts to apply decisions from regulators with comprehensively different systems and circumstances onto an Australian context. The Alliance would recommend some additional restrictions to ensure that this process does not inadvertently trigger additional, unnecessary re-registration and re-approval processes that are costly for the APVMA to administer and expensive for approval holders and registrants to comply with. The Alliance would recommend that:

- Decisions by overseas regulators that occurred before an active constituent or product was approved, re-approved, registered or re-registered should not be counted as 1 of the 2 overseas decisions. Any new information generated by that overseas decision would have been considered by the APVMA in the previous approval or registration decision. To allow that to count towards determining an additional re-approval or re-registration process is unnecessary; and
- Decisions by overseas regulators that reveal no new information beyond that already considered by the APVMA should not be counted. If a foreign regulator makes a decision that relies on information or data that has already been considered by the APVMA, there is no justification to trigger an additional re-registration or re-approval process in Australia.

The Alliance does however, support limiting reconsideration only to those decisions that have been made because of a concern about health, safety or environmental impacts while also taking into consideration differences in regulatory systems between regulators. Differences in the registration status of veterinary chemicals and related products in different countries are often mainly driven by commercial decisions of

chemical product registrants. Veterinary chemical product registrations can lapse without any driving force being on health, safety or environmental concerns. These commercial decisions made by companies must not be a trigger for regulatory action by the APVMA.

47B Advance notice of end of approval or registration

The Alliance supports measures to provide for notice – both publicly and to approval holders and registrants – about the end of an active constituent approval or end of a product registration. This process will allow both users and registrants to consider their options for either seeking re-approval or re-registration, or to invest in development and approval of alternative tools that meet their needs.

Schedule 3: Enforcement

The Alliance supports the expanded compliance toolkit for the APVMA that will be provided as a consequence of the amendments Bill. Ensuring that the APVMA has a comprehensive suite of graduated compliance tools that enable proportionate responses to compliance issues will be increasingly important. An effective compliance regime must ensure that the APVMA is not excessively focussed on technical compliance by registrants, but focussed on compliance by the entire industry, including those seeking to avoid regulatory controls.

Importantly, the APVMA must seek to deploy its scarce monitoring, compliance and enforcement resources in a manner that allows it to focus on those individuals and organisations that present the greatest risk.

The Alliance welcomes the focus on ensuring that the APVMA has adequate compliance powers. This needs to be matched by an enhanced strategic attitude towards compliance. Most compliance effort and resources should be focussed on individuals and organisations that seek to avoid regulatory scrutiny. In particular, significant compliance effort should be focussed on those that seek to import and supply products directly, avoiding registration requirements. The Alliance would include sections of the compounding pharmacy industry here.

Schedule 4: Data Protection

The Alliance supports proposals for improved data protection, which should offer incentives for delivering innovative new technology with veterinary chemical products in Australia. Appropriate data protection measures may also be able to facilitate better cooperation and collaboration between product registrants and approval holders and user groups.

In particular, the Alliance welcomes improvements in data protection for new active constituents and related new products being extended to 10 years. This reform is also essential to make veterinary chemical product data protection provisions contemporary with like Australian chemical regulators as well as those overseas.

The Alliance also welcomes provisions to more equitably treat innovative registrants of new veterinary chemical products and their generic competitors through better managing the issues related to spring-boarding applications.

MEDIA RELEASE - ATTACHMENT 6.

March 2012 – Delivering reforms that make a difference and achieve the better regulation of agricultural and veterinary chemicals.

http://www.animalhealthalliance.org.au/default.asp?V_DOC_ID=1819

MEDIA RELEASE - ATTACHMENT 7.

March 2012 - Delivering reforms that make a difference and achieve the better regulation of agricultural and veterinary chemicals – Impact on Farmers.

http://www.animalhealthalliance.org.au/default.asp?V_DOC_ID=1820

MEDIA RELEASE - ATTACHMENT 8.

8 August 2012 – Handicapping Australian Farmers.

http://www.animalhealthalliance.org.au/default.asp?V_DOC_ID=1808

MEDIA RELEASE - ATTACHMENT 9.

26 October 2012 – Pet health worry on the horizon.

http://www.animalhealthalliance.org.au/default.asp?V_DOC_ID=1812

MEDIA RELEASE - ATTACHMENT 10.

10 December 2012 – Red tape threatening animal health.

http://www.animalhealthalliance.org.au/default.asp?V_DOC_ID=1818