



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

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Chemicals and Plastics Study
Productivity Commission
Locked Bag 2
Collins Street East
MELBOURNE VIC 8003

Email: chemicalsandplastics@pc.gov.au

Productivity Commission Draft Research Report into Chemicals and Plastics Regulation

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. A list of member companies and their addresses is given in **Attachment A**. The Alliance welcomes the opportunity to comment on this Draft Research Report.

The Alliance comments fall into two parts. The first part (**Attachment B**) relates to the content of the Draft Research Report where we feel that text amendments are warranted. The second part (**Attachment C**) relates to our specific comments in relation to the actual draft recommendations in the Draft Research Report.

The Alliance is available to clarify any issues detailed in this submission.

Yours sincerely

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

ALLIANCE MEMBER COMPANIES

MEMBER	ADDRESS
Bayer Australia	PO Box 903 PYMBLE NSW 2073
Boehringer Ingelheim Pty Ltd	PO Box 1969 Macquarie Centre NORTH RYDE NSW 2113
Elanco Animal Health	Level 5 Avaya House 123 Epping Road MACQUARIE PARK NSW 2113
Fort Dodge Australia Pty Ltd	PO Box 6024 BAULKHAM HILLS BC NSW 2153
Intervet Australia Pty Ltd	PO Box 2800 BENDIGO MC VIC 3554
Merial Australia Pty Ltd	Locked Bag 5023 PARRAMATTA NSW 2150
Novartis Animal Health Australasia Pty Ltd	PO Box 2003 NORTH RYDE NSW 1670
OzBioPharm	c/-24 Parkhurst Drive KNOXFIELD VIC 3180
Pfizer Animal Health	PO Box 57 WEST RYDE NSW 2114
Schering-Plough Animal Health	Locked Bag 2234 NORTH RYDE NSW 1670
Virbac (Australia) Pty Limited	Locked Bag 6000 MILPERRA BC NSW 2214

PROPOSED TEXT AMENDMENTS

In relation to pages 78 (paragraph 3); 81 (paragraph 3 under the heading *Timeliness of APVMA assessments*) and 82 (paragraph 5) the Draft Research Report cites the Business Decisions Limited (2007) in relation to the animal health industry surveys. These surveys were funded by the Alliance member companies and were presented as part of the Animal Health Alliance (Australia) Ltd submission to this Productivity Commission study (refer to page 256 of this Draft Research Report, Table A.1, Submission no. 7). The Alliance would appreciate if appropriate reference to this effect was made on pages 78, 81 and 82 in the text of the Final Research Report.

Suggested wording to accommodate this request could be:

- For pages 78 and 82 – “*Surveys undertaken for the Animal Health Alliance (sub.7) by Business Decisions Limited (2007) suggest.....*”
- For page 81 – “*A report undertaken by Business Decisions Limited (2007) for Animal Health Alliance (sub.7) suggests.....*”

On page 78, paragraph 3, lines 3 and 4 of the Draft Research Report, reference is made twice to “efficacy testing”. A more appropriate term to use in both cases would be “efficacy evaluation” rather than “efficacy testing”. The word “testing” could be construed to mean assessing the performance of the product by actually using it in the field. The word “evaluation” more accurately reflects the fact that in relation to assessment of efficacy on behalf of the APVMA the expert evaluates scientific reports and publications relating to the usage of the product in the field that have been submitted by the product applicant.

On page 81, paragraph 2, under the heading *Timelines of APVMA assessments*, there is reference to submissions received that claimed that timeliness of APVMA assessments was a problem. The Alliance submission also referred to this issue (the Alliance submission, page 5, **ATTACHMENT B**, first bullet point, where we refer to increased timelines). The Alliance requests that “Animal Health Alliance (Australia) Ltd” (sub 7) be included in the list of references for this paragraph on page 81 of the Final Research Report.

On page 85, paragraph 1 under the heading *Utilisation of international linkages*, there is reference to “the Veterinary Medicines International Cooperation on Harmonisation program”. This is correctly called “the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) program”.

On page 206, Table 8.1 – **Self-regulatory agreements**, Animal Health Alliance (Australia) Ltd has been omitted from the “Partners” column for both the ChemClear® and the **DrumMUSTER** Agreements.

ALLIANCE COMMENTS ON THE DRAFT RECOMMENDATION

3. National policy formulation and system governance

DRAFT RECOMMENDATION 3.1

Subsequent to the COAG Ministerial Taskforce on Chemicals and Plastics Regulation having completed its reference, the Commonwealth, states and territories should establish, under the Australian Health Ministers' Conference, a Standing Committee on Chemicals, comprising representatives of all ministerial councils that have responsibility for chemicals regulation. It would:

- provide an ongoing forum for assessing:
 - the consistency of chemicals-specific policy settings across the various areas of concern, including public health, workplace and on-farm safety, transport safety, environment protection and national security
 - the effectiveness and efficiency of the overall chemicals-specific regulatory system
- address emerging issues, such as nanotechnology
- oversee the consistent application of chemicals hazard and risk-assessment methodologies
- make recommendations for specific actions by individual ministerial councils.

The Alliance position

The Alliance strongly supports this recommendation but would like to see recognition of the need for a mechanism for the impacted industries caught up by plastic and chemical regulation to have an opportunity to input into the proposed Standing Committee activities.

4. National hazard and risk assessment

DRAFT RECOMMENDATION 4.1

An objective of NICNAS should be to maximise net community benefit, and its assessment requirements and outcomes should be supported by analysis of the associated costs and benefits.

The Alliance position

The Alliance has no comment.

DRAFT RECOMMENDATION 4.2

The role of NICNAS should be limited to the scientific assessment of the hazards and risks of industrial chemicals.

The Alliance position

The Alliance has no comment.

DRAFT RECOMMENDATION 4.3

A technical advisory committee should be established within NICNAS, as a statutory requirement.

The Alliance position

The Alliance has no comment.

DRAFT RECOMMENDATION 4.4

NICNAS should implement a program to greatly accelerate the assessment of existing chemicals that:

- screens all existing chemicals to develop a list of high priority chemicals for assessment
- makes greater use of simulation techniques based on the hazards of chemical analogues
- urgently reviews the scope for recognising the assessment schemes of a range of other countries as 'approved foreign schemes'. Priorities should be the schemes operated by Canada, the European Union and the United States.

The incremental cost of this program, which is in the broader public interest, should be met from budget funding.

The Alliance position

While the Alliance has no specific comments on this recommendation in relation to NICNAS activities, we do have interest in relation to the Federal government's policy principle of "cost recovery" (www.finance.gov.au/finframework/docs/Cost_Recovery_Guidelines.rtf). The Alliance has a position that the APVMA review process of existing registered agvet chemicals should be funded from budget funding as there is an overall public benefit afforded by this activity. In relation to agvet chemicals however, the Federal government has adopted a policy of the agvet chemical industry funding the chemical review function of the APVMA via the existing sales levy on products. Recommendation 4.4 indicates that for NICNAS such funding for the same review activity should be met from budget funding. The Alliance believes that for this recommendation to retain credibility the Final Research Report will need to rationalize the different funding approach recommended here compared to that existing for APVMA.

DRAFT RECOMMENDATION 4.5

An objective of the National Registration Scheme for agricultural and veterinary chemicals should be to maximise net community benefit, and its assessment requirements and outcomes should be supported by analysis of the associated costs and benefits.

The Alliance position

The Alliance strongly supports this recommendation and sees the potential for tangible benefits with its implementation – particularly in relation to assessment of efficacy and trade components of submission dossiers.

DRAFT RECOMMENDATION 4.6

The National Registration Scheme for agricultural and veterinary chemicals should be extended to cover regulation of agricultural and veterinary chemical use after the point of retail sale, provided:

- the new national regime contains appropriate exemption provisions and is administered at state and territory level, to allow adequate flexibility to address local issues
- there is a commensurate reduction in regulatory burden at state and territory level.

The Alliance position

The Alliance is not opposed to the outcome attempting to be achieved with this recommendation however, we feel that further clarification is needed in the Final Research Report to identify the differences between crop chemical control of use issues and those for veterinary chemical products. In particular, the engagement of veterinarians in the supply and use of veterinary chemical products at State and Territory level is a risk mitigator. This is reflected in disproportionate number of "control of use" issues that frequently emerge being of a crop chemical nature. As such, in implementing this recommendation, government and regulators will need to be cognizant of the additional costs that this new role will place on APVMA. Similarly, a funding mechanism will need to be devised so to ensure that the veterinary chemical industry does not end up cross subsidizing the crop chemical industry on APVMA "control of use" activities. Comment to this effect in the Final Research Report would be helpful.

5. Public health

DRAFT RECOMMENDATION 5.1

The Australian Health Ministers' Conference should agree to separate responsibility for the scheduling and regulation of poisons from that of drugs. An intergovernmental agreement should be prepared between the Commonwealth, state and territory governments to:

- establish a Poisons Standing Committee under the Australian Health Ministers' Advisory Council to design the poisons schedules and the attached regulatory controls, and oversee the poisons regulatory process at all levels of government
- establish a Poisons Scheduling Committee of science experts under the Poisons Standing Committee, appointed by the Ministerial Council on the basis of their knowledge and experience, rather than on who they represent, to make decisions about the appropriate scheduling of poisons.

The Alliance position

While the Alliance is not opposed to this recommendation if it delivers overall regulatory efficiencies, we do have concerns that only a cursory approach has been given in the Draft Research Report to the fact that the veterinary chemical industry will need to be engaged, via their APVMA product applications or product reviews, with both resulting Scheduling Committees. The Alliance member companies have dealings with chemicals that will, based on their use and/or product formulation, be classified as poisons in some cases and drugs in other. Further clarity is required in defining what will constitute a "poison" and what will constitute a "drug" in this new process, and how will duplication of effort in scheduling be avoided.

DRAFT RECOMMENDATION 5.2

State and territory governments should:

- o uniformly adopt regulatory controls through either a template or model approach
- o adopt poisons scheduling decisions made at the national level directly by reference
- o report any variations to nationally-agreed poisons scheduling or regulatory decisions at the state and territory level to the Australian Health Ministers' Conference.

The Alliance position

The Alliance supports this recommendation.

DRAFT RECOMMENDATION 5.3

State and territory governments should exempt authorised users of poisons in the industrial environment from poisons controls. Such users should be regulated by appropriate workplace substances regulations.

The Alliance position

The Alliance supports this recommendation.

DRAFT RECOMMENDATION 5.4

The Ministerial Council for Consumer Affairs should initiate the development of a broadly-based hazard identification system, based on a clearing house approach, in line with the recommendations of the Productivity Commission's 2006 report on consumer product safety (PC 2006, recommendation 9.1). It should be coordinated by the Australian Competition and Consumer Commission, and take account of health and safety issues around chemicals released from consumer articles.

The Alliance position

The Alliance has no comment.

DRAFT RECOMMENDATION 5.5

The ACCC and NICNAS should negotiate formal arrangements for cooperation on issues regarding chemicals in consumer articles. These arrangements should include the establishment of a more systematic research program to identify and deal with the risks of chemicals in consumer articles.

The Alliance position

The Alliance has no comment.

DRAFT RECOMMENDATION 5.6

The Australian Government should transfer responsibility for the administration and enforcement of the Cosmetics Standard 2007 (Cwlth) from NICNAS to the ACCC.

The Alliance position

The Alliance has no comment.

DRAFT RECOMMENDATION 5.7

The Australian Government should add 'deemed-to-comply' provisions to the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 (Cwlth) for fully-imported cosmetic products that meet the cosmetic labelling requirements of specified countries that have labeling requirements that produce sufficiently comparable policy outcomes.

The Alliance position

The Alliance has no comment.

DRAFT RECOMMENDATION 5.8

The Ministerial Council on Drug Strategy should develop illicit drug precursor regulations for adoption by reference by all jurisdictions. The associated risk-based schedule of chemicals and apparatus subject to the regulations should be maintained by a committee of experts overseen by the Ministerial Council, and also be adopted by reference in each jurisdiction.

The Alliance position

The Alliance supports this recommendation.

DRAFT RECOMMENDATION 5.9

Maximum residue limits set by the APVMA, which take account of dietary impacts using methods agreed with Food Standards Australia New Zealand (FSANZ) and the Australian Government Department of Health and Ageing, should be automatically incorporated into the Australia New Zealand Food Standards Code. Any decision to the contrary by FSANZ and the Australia and New Zealand Food Regulation Ministerial Council should be based on a cost–benefit analysis and be reported publicly.

The Alliance position

The Alliance strongly supports this recommendation.

6. Workplace safety

DRAFT RECOMMENDATION 6.1

As part of its review of the National Standard and Code of Practice for the Control of Major Hazard Facilities, the Australian Safety and Compensation Council should:

- determine whether there is a case for regulation of Major Hazard Facilities beyond existing generic regulation in areas such as occupational health and safety, environmental protection and planning, based on cost–benefit analysis
- if such a case exists, identify strategies and opportunities for achieving greater consistency in the adoption and application of the Standard across jurisdictions, than what has been achieved to date.

The Alliance position

The Alliance supports this recommendation.

DRAFT RECOMMENDATION 6.2

The Commonwealth, state and territory governments should replace the existing systems of regulation of workplace hazardous substances and dangerous goods with a single system of regulations for the classification, labelling, provision of material safety data sheets and risk assessment for all workplace hazardous chemicals. The new system should be based on the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

Australia should not implement the new system until our major trading partners have implemented the GHS. In this context, the European Union has announced that it intends to move to a GHS-based system in 2015.

The Alliance position

The Alliance opposes this recommendation. The GHS has specifically excluded “pharmaceuticals” from its coverage and has not considered this group of chemicals in developing or implementing this new classification and labelling system. Veterinary pharmaceuticals – also known as veterinary drugs and veterinary chemicals – are classified as “pharmaceuticals” under the exclusion from GHS. The EU and USA have indicated that they are not intending to capture “pharmaceuticals” in future implementation of GHS in their jurisdictions. The Alliance cannot support a program that will impact on its members’ products when that program has specifically excluded its member’s products in devising that new program.

DRAFT RECOMMENDATION 6.3

Any new system for workplace hazardous chemicals labelling should recognize labels approved by APVMA as being sufficient for workplace requirements.

The Alliance position

The Alliance strongly supports this recommendation.

DRAFT RECOMMENDATION 6.4

In light of the agreement by the Workplace Relations Ministers’ Council (the Council) to replace the Australian Safety and Compensation Council with a new and independent national body, the Commission recommends:

- the new body be statutorily independent and made up of five to nine members appointed by the Commonwealth Minister on the basis of their qualifications and experience, and be constituted to reflect the broader public interest, rather than represent the interests of particular stakeholders
- the appointments by the Commonwealth Minister be approved by the Council
- the new body have the ability to appoint advisory bodies, noting the importance of consulting with employers, unions and all jurisdictions

- the Council be required to formally approve national standards and codes of practice prepared by the independent national body
- agreement by all jurisdictions to adopt, without variation, the standards and codes approved by the Council.

The Alliance position

The Alliance supports this recommendation.

7. Transport safety

DRAFT RECOMMENDATION 7.1

Jurisdictions should consistently adopt the Model Transport of Dangerous Goods Act and Regulations and should uniformly reference the Australian Dangerous Goods (ADG) Code.

The Alliance position

The Alliance supports this recommendation.

DRAFT RECOMMENDATION 7.2

In light of the risks of greater inconsistency in moving from template to model legislation for implementing the ADG7 package, the National Transport Commission should undertake a transparent public review of the consistency with which the new legislation, regulations and the ADG Code are adopted by jurisdictions.

In view of the strong governance arrangements for implementing national transport policy, and the successful implementation of dangerous goods transport policy under those arrangements to date, the Commission considers that responsibility for policy development and monitoring should, at this stage, remain with the National Transport Commission, reporting to the Australian Transport Council.

The Alliance position

The Alliance supports this recommendation.

DRAFT RECOMMENDATION 7.3

The current review of the Australian Explosives Code (AEC) should be expanded to include jurisdictional legislation and regulations for explosives transport, and should lead to nationally consistent legislation and regulations and a uniformly adopted technical code.

Future revisions to the AEC should be undertaken separately from, but in parallel with, revisions to the regulation of other dangerous goods. In the longer term — if successful interjurisdictional harmonisation of explosives transport legislation regulations and technical code is achieved — the regulation of dangerous goods and explosives transport should be combined.

The Alliance position

The Alliance has no comment.

DRAFT RECOMMENDATION 7.4

The Australian Dangerous Goods Code should be available free on the internet and at avoidable cost for hard copies. The resultant revenue loss for the National Transport Commission should be offset by increased jurisdictional contributions. Pricing of the Australian Explosives Code should also follow these principles.

The Alliance position

The Alliance supports this recommendation.

8. Environment protection

DRAFT RECOMMENDATION 8.1

The Environment Protection and Heritage Council (EPHC) Chemicals Working Group should continue to assess the need for a national framework for the management of chemicals in the environment.

If this work demonstrates that such a framework would improve effectiveness and efficiency, the Commonwealth, state and territory governments should negotiate an intergovernmental agreement to create an independent standard-setting body reporting to the EPHC.

- This body would develop standards for the environmental risk management of chemicals that the states and territories would adopt by reference, and have the power to ban or phase out chemicals, subject to appropriate cost–benefit analysis.
- Members of the environmental risk management standard setting body should be appointed based on their qualifications and experience. The body should be constituted to reflect the broader public interest and have the ability to appoint advisory bodies as necessary.

The Alliance position

The Alliance opposes this recommendation. The intent potentially to establish an independent standing body reporting to EPHC that could ban or phase out chemicals would duplicate the existing role of APVMA. APVMA can review existing chemical products taking into consideration the impact of their “supply” and use in the Australian environment. In relation to chemical products under review, the APVMA, can, among other things, force the modification of chemical formulations, amend approved label use patterns, restrict supply and possession, and withdraw product registration and label approval.

9. National security

DRAFT RECOMMENDATION 9.1

A nationally uniform approach to conducting security checks for access to security sensitive ammonium nitrate should be implemented, irrespective of other harmonisation measures. This process should be managed by the Australian Government, through AusCheck. The information should be shared across jurisdictions using a database that reports current, refused or revoked security clearances.

The Alliance position

The Alliance has no comment.

DRAFT RECOMMENDATION 9.2

State and territory governments should consider the following improvements for achieving greater national harmonisation of the security sensitive ammonium nitrate (SSAN) regulations:

- removing major inconsistencies in reporting requirements
- basing storage requirements on the internationally agreed physical properties of SSAN, provided security controls are met
- ensuring that a single security plan can be lodged for transporting SSAN nationally
- making licence durations nationally consistent
- regulatory agencies committing to, and reporting on, timeframes for assessing licence applications.

The Alliance position

The Alliance has no comment.

DRAFT RECOMMENDATION 9.3

State and territory governments should not add any additional security sensitive chemicals to the current security sensitive ammonium nitrate regulations.

The Alliance position

The Alliance has no comment.

DRAFT RECOMMENDATION 9.4

Australian governments should establish an agreed framework for assessing the security risks and appropriate control measures associated with chemicals of security concern. This framework should incorporate strong governance arrangements, underpinned by an intergovernmental agreement, that ensure control measures are implemented consistently across jurisdictions. Once established, this framework should be used to re-examine the controls on ammonium nitrate.

The Alliance position

The Alliance supports this recommendation.