



Australian Government

Australian Pesticides and  
Veterinary Medicines Authority

3 April 2008

The Secretary  
Senate Select Committee on Agriculture and Related Industries  
PO Box 6100  
Parliament House  
CANBERRA ACT 2600

Dear Sir/Madam

**Inquiry into pricing and supply arrangements in the Australian and global chemical and fertiliser market**

Thank you for the invitation to make a submission to this inquiry. The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator for agricultural and veterinary (agvet) chemicals. This submission provides a background to the Australian agvet chemical industry and current regulatory arrangements for agvet chemicals in Australia. It also draws reference to prior and ongoing reviews relevant to chemicals regulation.

***Background***

The APVMA is an Australian Government Statutory Authority within the portfolio of the Department of Agriculture, Fisheries and Forestry. It regulates the supply of agricultural and veterinary (agvet) chemicals in the Australian marketplace up to and including the point of retail sale. Each State and Territory regulates the use of those chemicals in its jurisdiction. This arrangement is the "National Registration Scheme" (NRS) which was established by the inter-governmental agreement of the Commonwealth, State and Territory agriculture Ministers in September 1995. The NRS is established in this way because of the Constitutional limitations on the Commonwealth's ability to legislate over agvet chemicals. The regulatory framework is a complementary one with a shared division of responsibilities between the Commonwealth and the States and Territories.

The APVMA's mission is to protect the health and safety of people, animals and crops, the environment, and trade and support Australian primary industries through evidence-based effective and efficient regulation of agricultural and veterinary chemicals. It does this through its evaluation and registration of agricultural and veterinary chemical products; its permits scheme; the review of older chemicals or chemicals for which concerns have been raised to ensure they continue to meet contemporary standards; as well as ensuring compliance, both during manufacture and in the market. Agricultural

and veterinary chemical products are vital for the efficient production of commodities by the primary sector.

### ***Australian situation***

The Australian agricultural and veterinary chemical market is relatively small on a world scale. The Australian market comprises less than two per cent of the global distribution of agricultural and veterinary chemicals. Even so, the regulatory system must still deliver outcomes comparable to those of other first world nations in terms of safety to consumers and the environment. It is also imperative that the system be recognised internationally as effective if Australia's export trade in agricultural commodities is to be sustained.

The Australian agvet chemical industry is diverse comprising importers, manufacturers, packagers, wholesalers and retailers of a variety of products including veterinary medicines, companion animal products, pesticides and other agricultural products, chemicals for home garden and household use, pool and spa chemicals, timber preservatives and marine antifouling paints. The size of companies ranges from extremely small businesses to large multinational companies.

For the financial year 2007/08, a total of 810 companies renewed registrations on a total of 8,346 agvet chemical products, and the majority (730) of these companies were small companies (classified as small by the APVMA where total sales of all agvet chemicals sold by a company is less than \$5 million).

In the financial year 2006/07 approximately half (54%) the products in the market earned less than \$25,000 in sales, and approximately one-third (32%) of the registered products had no sales. Data relating to the annual value of disposals (wholesale sales of agvet chemicals) aggregated by product type are published in the APVMA gazette annually<sup>1</sup>.

The importation of chemical products and active constituents is significant to the Australian agvet chemicals industry with sources such as China and India featuring strongly in terms of active constituent manufacturing. For this reason movements in global chemical pricing can have a significant effect on the retail price of chemicals in Australia.

### ***Benchmarking APVMA performance***

In 2005 the APVMA sought to benchmark key aspects of its operations with those of its counterparts in other countries. Even given the differences in activities between the various agencies and their differing statutory responsibilities, the informal benchmarking study showed that the APVMA compared favourably with the equivalent Canadian, United States and United Kingdom regulatory authorities in terms of application fees,

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<sup>1</sup> The value of disposals for the financial year 2005/06 for agricultural and veterinary chemicals respectively are available at [http://www.apvma.gov.au/gazette/0706downloads/agsales\\_p62.pdf](http://www.apvma.gov.au/gazette/0706downloads/agsales_p62.pdf) and [http://www.apvma.gov.au/gazette/0706downloads/vetsales\\_p63.pdf](http://www.apvma.gov.au/gazette/0706downloads/vetsales_p63.pdf).

timeframes and timeframe performance. These results supported the outcomes of an earlier formal benchmarking study conducted in 1998 by Health Canada on behalf of the Pest Management Regulatory Agency (PMRA), which compared functions, application throughput, decision timeframes and costs of the pesticide regulatory systems in Australia, Canada, the United Kingdom and the United States. With regard to application fees for agricultural chemicals, the current fee in Australia for the assessment of a product involving new chemistry (a chemical that has not previously been considered) for use on a food crop is \$48,860 – the cost of a comparable application in the United States is \$516,300 US<sup>2</sup>.

The international competitiveness of the Australian regulatory system for veterinary chemicals has recently been confirmed by a qualitative survey commissioned by the International Federation for Animal Health and conducted by Business Decisions Limited. Business Decisions Limited's report, '*Benchmarking the Competitiveness of the Australian Animal Health Industry (March 2007)*', found that chemical industry respondents perceived that the size of the Australian market is the biggest obstacle to innovation rather than the existing regulatory framework. This was in contrast to all other regions covered by the research where respondents identified the regulatory framework as being the biggest obstacle to innovation.

In 2006 the APVMA was the subject of a comprehensive performance audit by the Australian National Audit Office that assessed whether the APVMA was delivering its key regulatory functions effectively. The performance audit report<sup>3</sup> acknowledged the various initiatives the APVMA had introduced in recent years to improve the effectiveness of its operations and made six recommendations. The APVMA welcomed the report and is implementing each of the recommendations<sup>4</sup>. The arena of chemicals regulation is constantly changing and the APVMA believes that the performance audit has provided valuable recommendations for further improvements to its operations.

### ***International engagement***

The APVMA actively engages with similar regulators of other OECD countries to facilitate consistency and improved efficiencies wherever possible. We are currently involved in a number of work-share projects with similar regulators of other OECD member countries and have signed memoranda of understanding with a number of our counterparts. This international cooperation is intended to harmonise data assessment procedures and data requirements between comparable regulators to facilitate greater

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<sup>2</sup> APVMA application fees are set out in the Manual of Requirements and Guidelines (Volume 2) available from the APVMA website at <http://www.apvma.gov.au/industry/MORAG.shtml>. Application fees in the United States are available from the United States Environmental Protection Agency website at [http://www.epa.gov/pesticides/regulating/fees/tool/resources/dt\\_logic\\_and\\_fee\\_category\\_list\\_1.pdf](http://www.epa.gov/pesticides/regulating/fees/tool/resources/dt_logic_and_fee_category_list_1.pdf).

<sup>3</sup> Available at [http://www.anao.gov.au/uploads/documents/2006-07\\_Audit\\_Report\\_14.pdf](http://www.anao.gov.au/uploads/documents/2006-07_Audit_Report_14.pdf).

<sup>4</sup> Further information on the APVMA's implementation activities is available at [http://www.apvma.gov.au/about\\_us/anao\\_report.shtml](http://www.apvma.gov.au/about_us/anao_report.shtml).

work sharing and improve the international 'portability' of scientific data with respect to chemical products. These activities work to directly facilitate international consistency and relevance in terms of Australian chemical regulation activities.

### ***Cost Recovery***

Since 1996 the APVMA has been operating on a full cost recovery basis. This arrangement was determined by the Australian Government in conjunction with all state and territory governments and is set out in the agreement that establishes the NRS. As a consequence of the complex inter-governmental governance arrangements for the NRS, changes to the legislation and the over-arching policy framework, including the cost recovery arrangements, may only be made with the consent of all signatories to that agreement.

The last review of the APVMA's fee structure occurred in 2005 when a Cost Recovery Impact Statement (CRIS) considered various policy issues and fee options<sup>5</sup>. The CRIS process included detailed and comprehensive consultation with the agvet chemical industry. The CRIS recommended that the cost of approvals and registration be subsidised with the applicant only paying 40 per cent of the actual assessment cost and the remainder being recovered across the life of the product via the levy on wholesale sales<sup>6</sup>.

It is noteworthy that in its support for the nominal fee of 40 per cent of the cost of assessing applications, the then Signatories Working Group<sup>7</sup> considered that a higher level of cost recovery via the application fee could 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. Various sections of the agvet chemical industry have opposed the 40 per cent subsidisation level and the use of the levy as the balancing factor and argue that this constitutes inappropriate cross-subsidisation. Other submissions received as part of the CRIS process proposed application fees varying from zero to 100 per cent of the cost of assessing the application.

The cost recovery arrangements of the APVMA are due for review by the end of the 2007–08 financial year. That review (currently occurring) will revisit the appropriateness of the cost recovery framework.

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<sup>5</sup> The 2005 Cost Recovery Impact Statement is available at [http://www.daff.gov.au/\\_data/assets/pdf\\_file/0009/146718/Certified\\_Final\\_CRIS.pdf](http://www.daff.gov.au/_data/assets/pdf_file/0009/146718/Certified_Final_CRIS.pdf).

<sup>6</sup> Information on the annual fee for registered products and the levies charged on registered product sales is available from the APVMA website at <http://www.apvma.gov.au/registration/feesmain.shtml>. Information on application fees is available in APVMA Manual of Requirements and Guidelines (Volume 2) available at <http://www.apvma.gov.au/industry/MORAG.shtml>.

<sup>7</sup> The Signatories Working Group was a sub-committee of the Product Safety and Integrity Committee.

## *Reviews of regulation*

It is acknowledged that both the direct (for example application fees, levies etc) and indirect (for example the costs of compliance) costs of regulation have a contributory effect on industry profit and the market prices of chemicals. Although the costs of regulation are initially born by the chemical industry such costs are generally subsequently passed on to chemical users in the form of higher prices.

In 2005 the then Prime Minister and Treasurer appointed a taskforce to consider options for alleviating the compliance burden on business from Government regulation. In early 2006 the taskforce delivered its report 'Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business'<sup>8</sup>. The report made five recommendations relevant to agvet chemical regulation. All the recommendations of the taskforce were addressed in a comprehensive Australian Government response<sup>9</sup>. The APVMA has since been participating in a number of activities to support those recommendations.

In response to recommendation 4.58, develop an integrated national chemicals policy, COAG established a Ministerial taskforce to consider chemicals and plastics regulation. In addition the then Government agreed to Commission an independent study of regulation in the sector to be conducted by the Productivity Commission – that study will assist to inform the Ministerial taskforce.

The Productivity Commission has subsequently completed an annual review of regulatory burdens on businesses in the primary sector<sup>10</sup> and is currently conducting the study into chemicals and plastics regulation<sup>11</sup>. The APVMA has actively participated in the annual review and the chemicals and plastics study and has made submissions to both investigations – these are available from the Commission's website. The APVMA's submission to the Chemicals and Plastics study outlines the current reform agenda for agvet chemical regulation, in both the operational and policy arena.

In its report on the Regulatory Burdens on Business (Primary Sector) and subsequent draft report on Chemicals and Plastics Regulation the Commission has highlighted that there are several grounds for government policy intervention in the chemicals industry, including the public good argument for the protection of public health, the environment and national security. The Commission has also highlighted that all regulation has a cost but that unnecessarily burdensome regulations, the focus of their investigations, are a smaller subset of costs that are over and above the necessary costs inherent in meeting policy objectives.

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<sup>8</sup> The Report of the Taskforce on Reducing Regulatory Burdens on Business is available at <http://www.regulationtaskforce.gov.au/finalreport>.

<sup>9</sup> A copy of the Australian Government's response is available at [http://www.treasury.gov.au/documents/1141/RTF/Reducing\\_Regulatory\\_Burdens\\_on\\_Business\\_Final\\_Government\\_Response.rtf](http://www.treasury.gov.au/documents/1141/RTF/Reducing_Regulatory_Burdens_on_Business_Final_Government_Response.rtf)

<sup>10</sup> The homepage for the Annual Review of Regulatory Burdens on Business – Primary Sector is <http://www.pc.gov.au/study/regulatoryburdens/primarysector>.

<sup>11</sup> The homepage for the Chemicals and Plastics Regulation Study is <http://www.pc.gov.au/study/chemicalsandplastics>.

Through its ongoing reform agenda the APVMA has sought to produce regulatory efficiencies and reduce unnecessary regulatory burden and cost within the scope of its operations. The APVMA is committed to assisting the Australian Government's objective to minimise 'red tape' without compromising the overall policy objectives of chemicals regulation and welcomes the reforms that may flow from the above-mentioned reviews to achieve that objective.

The APVMA welcomes the opportunity to discuss matters relating to the regulation of agvet chemicals with the committee and looks forward to participating in any relevant hearings relating to this inquiry.

The APVMA contact for our input to this inquiry is Dr John Paul (ph: 02 6210 4738 email: [john.paul@apvma.gov.au](mailto:john.paul@apvma.gov.au)).

Yours sincerely

A handwritten signature in cursive script that reads "Eva Bennet-Jenkins".

Dr Eva Bennet-Jenkins  
Chief Executive Officer