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1/04

Message from the CEO

Welcome to the first edition of the APVMA's new electronic Newsletter. Regular communication with our stakeholders is particularly important for us and the Newsletter aims to reach people directly and more frequently than we have been able to do in the past. The Newsletter replaces the APVMA News magazine and will alert readers in a more timely way to important issues that the APVMA is currently dealing with and provide useful links to further information on the website. I trust that you will find the Newsletter a valuable addition to our communication efforts and would welcome your feedback on it.

Dr Joe Smith

Data protection is on its way

The APVMA is in the process of preparing for the start of the new data protection regime on 1 January 2005. We are currently amending requirements, guidelines, forms and internal processes and discussing changes with our advice providers. Towards the end of

November the APVMA will be holding data protection information seminars and will also be posting updates of new requirements and guidelines on the APVMA website. Please contact Gavin Hall on 02 6272 4405 if you have any questions.

APVMA Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products

During August and September the APVMA presented industry seminars on implementing the new scheme in Canberra, Melbourne and Perth, attracting approximately 130 people.

The APVMA has decided to maintain the requirement that all active constituents used in agricultural chemical products (at time of registration and post-registration) must come from a manufacturing site that has been assessed by the APVMA and included in the Record of Approved Active Constituents. This decision takes into account feedback received at recent industry seminars.

The requirement will be included in the conditions of product registration and active approval. These will form the basis of ongoing APVMA compliance activity. http://www.apvma.gov.au/actives/actives_sep_2004.shtml - includes a Questions and Answers page. Announcement of the re-consideration of existing active approvals and related product registrations was made in the September gazette

www.apvma.gov.au/gazette/gazette0409p76.shtml

Early despatch of draft levy sales declarations

Draft Levy Sales Declarations seeking product sales for Calendar Year 2004 will be dispatched earlier next year to assist earlier forecasting of revenue.

The APVMA will dispatch the draft Sales Declarations to Registrants in early January 2005 (not April as in previous years). The completed Sales Declarations will need to be returned to the APVMA by the end of February 2005. Levy Assessment notices will then be generated and sent to Registrants.

In preparation for a likely move to sales declarations based on Financial Years (not Calendar Years) two periods will be requested:

Sales from 1 January 2004 - 30 June 2004 and
Sales from 1 July 2004 - 31 December 2004.

The earlier submission of sales data will improve the APVMA's budget forecasting.

While the submission date for sales has been brought forward there will be no change to the due date for payments of the levy liability.

Questions should be directed to the Manager Finance and Administration, Tanya Evans, Ph: 02 6272 3779.

Swimming Pool Ionisers

In March this year the APVMA took recall action against several suppliers of unregistered copper-silver electrodes for use with their pool ionising systems. Some suppliers challenged the APVMA's position that the electrodes must be registered. The Administrative Appeals Tribunal considered this issue for three ionising systems. The Tribunal determined that the electrodes and the proprietary oxidiser used with the Questa Poolfresh Plus and Aquamatics systems require registration. It also determined that the electrode used with Floatron requires registration.

These decisions confirm the APVMA's position.

There is more information about this, including links to the Tribunal's decision, in the 'Latest news' section of the APVMA website www.apvma.gov.au

GMP compliance of overseas veterinary chemical product manufacturers

A consultation (draft) Regulation Impact Statement on Assuring the Enduring GMP Compliance of Overseas Veterinary Manufacturers was released for public comment in early September. The closing date for submissions was 8 October 2004 and these are now being considered.

www.apvma.gov.au/qa/GMP_draft_RIS.shtml

Veterinary medicine recall in the U.S.

An information sheet has been issued on the APVMA response to the recall in the United States of the veterinary medicine 'ProHeart 6' used to prevent heartworm in dogs.

www.apvma.gov.au/qa/proheart.shtml

APVMA-authorized GMP auditors

An updated list of APVMA-authorized GMP auditors is now available

www.apvma.gov.au/qa/gmp_auditors.pdf

Law Enforcement Liaison Breakfast

On 16 September the APVMA's Compliance Team hosted a government law enforcement liaison meeting that included members of the Australian Customs Service, the Federal Police, Dept of Environment and Heritage, the Australian Crime Commission and other agencies. The meeting is held every 6 months for regulatory staff from different fields to share current experiences of law enforcement in government agencies.

Tasmanian company and its director fined for supply of unregistered veterinary medicines

Tasmanian company, Group A International Pty Ltd and its Director were found guilty in the Hobart Magistrates Court on 2 August 2004 of supplying unregistered veterinary medicines. This follows a lengthy investigation by the APVMA into the advertising and sale of various unregistered veterinary medicines intended for use in the racing industry and for domestic animals. The company and its director were convicted and received a total fine of \$20,500.
www.apvma.gov.au/qa/supply_unregistered.shtml

Minor use reform

Minor use reform is a key focus for the APVMA currently, with a range of actions underway to address minor use issues and improve the permit scheme. For regular updates on our minor use reform program see previous and future editions of the minor use news at:
www.apvma.gov.au/minor_use/minor_use_news.shtml

Proposed changes to notification of issued permits for product registrants

With the regular release of Minor Use News that contains all issued minor use permits for the previous month the APVMA is proposing to cease sending hard copies of permits to registrants where those permits include their product(s). It is considered more effective if interested registrants monitor the monthly editions of Minor Use News to obtain copies of permits issued covering their products. This

proposal only affects issued permits, the APVMA will continue to seek manufacturer comments on pending applications in the usual manner where necessary. It is proposed that hard copies of permits issued will only be circulated to permit holders/applicants. The APVMA welcomes any comments or suggestions on this proposal, and these may be directed to Alan Norden – Minor Use Project Officer, Ph: 02 6272 3726.

Chemical review forum

The APVMA is conducting a one-day forum in Canberra on 24 November 2004 to focus on the APVMA's Chemical Review Program and its implications for users. In addition to its registration functions, the APVMA also reviews concerns about existing registered products and approved actives. Users can be affected by the outcomes of such chemical reviews through changes to labels, restrictions to a product's use, or even removal of products from the marketplace. The purpose of

the forum is to explain the review process and its implications for chemical users, outline the scope for user involvement in the review process, and to explore concerns of user and industry groups on review issues. The APVMA is the process of contacting user groups with information about the forum. For further details regarding participation at this forum, please contact Sara Broomhall, Evaluator Pesticides Review, Ph 02 6272 5638.

APVMA's quality people management initiatives acknowledged

The APVMA has followed up its ACT Division success by winning the Australian Human Resources Institute's 2004 National Award for Excellence in People Management in the public sector/small enterprise category. The award was presented in Sydney in recognition of the integrated way the APVMA uses innovative people management as a strategic tool to help achieve corporate objectives. The AHRI Awards for Excellence in People Management have been running for a number of years and are aimed at identifying and rewarding

organisations that have demonstrated a strategic and integrated approach to human resources and honour the contribution it makes to the achievement of business outcomes. The National Awards involved State finalists from across Australia in the public and private sectors. Winners were chosen by a national panel of senior people from the private and public sectors and academia assessing the finalists against specific selection criteria. For more details on the award see the AHRI announcements at www.awards.ahri.com.au

Prior Informed Consent (PIC) and Persistent Organic Pollutants (POPs)

Australia is a recent signatory to two international treaties related to chemical management and is obliged to comply with its responsibilities under each convention. The obligations came into effect from 18 August 2004.

The Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade aims to provide an efficient method for exchanging information about a small number of banned or severely restricted industrial chemicals and pesticides between participating countries.

The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from persistent organic pollutants (POPs). These are a set of chemical substances that are toxic, persist in the environment for a long period of time and bioaccumulate in the fatty tissues as they move up the food chain. In implementing the Convention, Governments are required to take measures to eliminate or reduce the release of POPs into the environment.

More information on the conventions can be found on the Australian Department of Agriculture, Fisheries and Forestry website [Stockholm and Rotterdam Conventions](#)

Soil biology in agriculture

The APVMA recently presented a paper on registration requirements for soil biological products to a workshop on current research into soil biology in agriculture at the Tamworth Sustainable Farming Training Centre. Speakers from around Australia presented findings of research programs on soil biology. The workshop was well supported, highlighting a high level of interest in soil biology.

Many products applied to the soil are considered to be agricultural chemicals products under the Agvet Code, especially if they are intended to control soil pests or diseases. The APVMA has published guidelines for the registration of biological agricultural products, available at

www.apvma.gov.au/guidelines/bioagprod.shtml

The role of biology in the management of urban & commercial pests in Australia

On 30 September members of the APVMA Insecticide Evaluation Team participated in a symposium addressing the role of biology in the management of urban and commercial pests. The symposium was held at the University of New South Wales and was organised by the Centre for Entomological Research and Insecticide Technology (CERIT). The high quality presentations covered a wide range of pests including termites, cockroaches, rodents, spiders, ants, bed bugs, stored product pests and birds, and provided a valuable insight into the wide ranging issues faced by pest managers.

Of particular interest was the reported dramatic resurgence of the bed bug which is thought to have been aided by increased globalisation (transport via luggage, clothing etc) and changes in pest control practices that may have inadvertently favoured bed bugs. Whilst a number of products are registered for bed bug control, infestations are very difficult to eliminate. Despite this apparent resurgence, research into bed bug control is reportedly virtually non-existent (a bed bug fact sheet is available via

www.medent.usyd.edu.au

APVMA's approval of active constituents

Amendments to the Agvet Code last year enable the APVMA, in certain circumstances, to approve an active constituent without the need for an application. To do so the APVMA must be satisfied that the active constituent is well known, in common use and has a history of safety in its use.

More information

www.apvma.gov.au/actives/approval_s14.shtml

Chemical review update

The APVMA is currently reviewing the following chemicals:

1080	endosulfan
2,4D	fenamiphos
CCA	fenthion
atrazine	fenitrothion
azinphos-methyl	fipronil
benomyl	macrolide antibiotics
carbaryl	maldison (malathion)
carbon disulfide	methidathion
chlorfenvinphos	methamidaphos
chlorpyrifos	methiocarb
diazinon	molinate
dichlorvos	omethoate
dimethoate	paraquat
dimetridazole	parathion-methyl
diquat	sheep ectoparasiticides
diuron	virginiamycin

www.apvma.gov.au/chemrev/chemrev.shtml

New on the APVMA website:

New veterinary guideline: www.apvma.gov.au/guidelines/immunobiological_formulation_change.pdf

Final version, storage stability data for veterinary products: www.apvma.gov.au/guidelines/storage_stability.pdf

New Animal Residue Data Sheet: www.apvma.gov.au/residues/ARDS-flupropanate.pdf

Announcement of AHRI Award: www.apvma.gov.au/about_us/ahri.shtml

List of GMP auditors: www.apvma.gov.au/qa/gmp_auditors.pdf

Standard for the active Chlorothalonil: www.apvma.gov.au/actives/standard_chlorothalonil.shtml

APVMA gazette October issue: www.apvma.gov.au/gazette/gazette0410.shtml

MRL Standard - October 2004 issue: www.apvma.gov.au/residues/mrl_standard.shtml