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ACVM News & Views

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ACVM Workshop

The latest ACVM workshop for registrants and others, which was held on 23 February 2017 in Auckland, had 102 attendees. It was great to see so many participants although having 20 people who didn't let us know they were coming caused some major scrambling for the caterers and organisers.

We provided presentations on a number of different areas including:

- the registration process
- protection of confidential information
- MRLs
- registration statistics
- international activities.

In the afternoon, the workshop split between agricultural chemicals and veterinary medicines. Feedback from attendees was very positive.

The PowerPoint presentations given on the day were uploaded to our website as a PDF. There was a linking glitch with the original upload, but this has been fixed and the PDF has been expanded to include the presentation on veterinary medicine chemistry and manufacturing.

NEW! PDS and Labels

As advised at the recent ACVM workshop, we will no longer accept single page amendments to Registration and Product Datasheets (PDS) and labels.

Complete signed and dated PDS and label documents must be supplied with ALL applications relating to registrations. This is to ensure complete versions of these documents are reviewed and approved with each application.

Manufacturing Workshops

Preliminary planning for two workshops on manufacturing is underway:

- Wellington workshop -- Friday, 28 July
- Auckland workshop -- date to be decided

If you would like to be notified when registrations are open or have any questions or suggestions for topics, please email Holly Jebault-Jones. (holly.jebault-jones@mpi.govt.nz)

Ministry for Primary Industries
Manatū Ahu Matua

Annual Fees & Registration Renewals

We wish to remind registrants that annual fees are separate from renewal of product registrations. Payment of annual fees does not renew a product registration.

Annual fees

Annual fees are a fixed fee payable by registrants, based on the number of products registered to them. They are paid in advance, e.g. the current annual fees run from 1 October 2016 through 30 September 2017. Reminder letters are sent to registrants in June of each year, with payment due in September. The reminder letter asks you to view your list of registered products on the public register and advise us if you wish to de-register any of your products. Please note it is the responsibility of the registrant to ensure that their contact details are current, and to advise us of any change.

Registration renewals

Trade name products currently have a registration life cycle of three years, and must be renewed prior to the end of the three-year period. Expired products will be removed from the public register. It is illegal to import, sell, use, or manufacture a trade name product removed from the register.

Registration renewal applications are made to renew the registration period and set a new registration expiry date – no other changes can be made in a registration renewal application. To enable trade name products to remain legally registered, registrants must allow sufficient time for us to process and grant their registration renewal applications.

When should I submit a registration renewal application?

Registration renewal applications should be submitted no later than three months prior to the expiry date.

Registration date and expiry date can be found on your product's Certificate of Registration.

Variation application(s) submitted concurrently with a renewal application cannot be accepted if the registration is due to expire within three months from the date of submission. In this case, precedence must be given to processing the renewal application to ensure your product stays legally registered. For registration renewal applications, the label plus the Registration and Product Datasheet (PDS) submitted must be the same as that currently approved. The exception for labels is if mandatory label statements have changed since the last approval. In these cases we advise updating mandatory label statements (e.g. updating the management of residues mandatory statement from "It is an offence for users of this product to cause residues exceeding the relevant MRL in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards" to "It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels for Agricultural Compounds".

If you wish to also submit a variation application, these should be submitted as soon as possible after you receive your registration renewal approval. Should you wish to submit any type of variation application within four-to-five months of the registration expiry date, we advise that you must submit a complete PDS and label with the appropriate variation application forms. Upon granting an approval, MPI will then issue a new Certificate of Registration thatwill include a new expiry date, and provide an approved PDS and approved label.

What do I need to submit for a registration renewal application?

A complete registration renewal application comprises:

- a complete signed and dated application form (Renewal of registration of an ACVM trade name product ACVM 1R)
- a complete label
- a complete signed and dated PDS. Please ensure you use the latest version of the appropriate PDS template (version August 2014), which is on our website.

What do I do if I have a product registered with Condition 86 and /or Condition 101?

For risk management purposes, sometimes products are registered with conditions requiring provision of additional information. The most common of these conditions of registration are:

Condition 86

The registrant must provide a batch analysis, which confirms that the product meets the approved release specifications, from the first production batch at the new manufacturing site to the Ministry for Primary Industries for approval prior to sale of product from this new site.

Condition 101

The registrant must provide additional information specified* by the Ministry for Primary Industries at or before the expiry of the current product registration period.

* Information is specified in the letter of registration.

We advise that you must still comply with these conditions by providing the information as specified.

Renewal applications and enquiries

To streamline the receipt of registration renewals, please direct all renewal queries and renewal applications to regRenewalACVM@mpi.govt.nz

FYI

MRL Notice

The next MRL promulgation round and the associated draft for consultation is now complete. The draft contains 37 proposed changes to the MRL Notice, including:

- 29 new or amended compound entries
- 1 new agricultural chemical exception from compliance with an MRL
- 1 amended residue definition, and
- 5 administrative changes to entry content.

This round of MRL promulgations will include the reduced MRLs for six organophosphates and carbamates as a result of the OPC reassessment.

The sixty day consultation period will commence on 31 March.

Assessment alignment update

As announced in the December 2016 issue, we have been working on changes to our registration procedure to allow applicants to submit one application form for biosecurity and ACVM registration requirements. A trial using the new application with some registrants will take place prior to taking the changes live. As soon as any issues have been ironed out, the alignment will be transferred to all application types including registration renewals, provisional registrations, research approvals and special circumstance requests. MPI hopes to have the alignment complete by the end of 2017. Costs will be combined so applicants will be charged once.

Upcoming consultation

A new ACVM Act Notice, **Agricultural Compounds Exempt from Registration,** will be prepared for public consultation once it has completed the internal authorisation process.

This Notice specifies in more detail the requirements in the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 for agricultural compounds (including veterinary medicines) exempted from registration under those Regulations.

While the Regulations specify requirements for the exempt agricultural compound, this Notice specifies requirements for the person(s) responsible for the exempt agricultural compound to ensure that the compound requirements are met.

Introducing...

We are pleased to welcome our new team members

Christian Morales, Auditor Regulatory Programmes

"Born and raised in Mexico City, I'm an Industrial Engineer with a post-graduate Diploma in Production Management. I worked in Good Manufacturing Practice areas for thirteen years, mainly Quality Assurance and Manufacturing, five years of which I spent as a Manager of Packaging Operations.

I came to New Zealand with my wife three years ago as we wanted to live and study in different countries around the world. We decided, however, to grow roots in New Zealand when we realised that we had fallen in love with the country and its people.

I joined MPI in December 2016, following a desire to increase my experience in auditing practices, which I found in my previous experience very interesting and fulfilling.

In my spare time I enjoy travelling, writing and role play videogames."

Sara Van Rooy, Adviser Approvals Enquiries

"I officially joined the Approvals team in January this year but have worked at MPI for two years previously in different areas, including consumer enquiries (info), organisational communications and plant imports.

My role in the Approvals team is managing the mailbox and phone line, and I do my best to answer all your questions. I also process applications for class determinations under the ACVM Act and help with registrations under the Food Act 2014.

I'm a born and bred Wellingtonian with a strong Dutch cultural heritage. I have a degree in Sociology and Social Policy from Victoria University and am always eager to learn new things -- hence my bouncing around MPI gaining knowledge in a range of areas. For the past three years I've spent my weekends as a volunteer for the Wellington SPCA, and when I'm not doing that you can find me pottering in the garden or doing something crafty."

Right of Review

Section 77A of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 provides a right of review of specific decisions made under delegated authority. This means that, if the Director-General does not personally make the decision and leaves it to a person to whom the power to make the decision has been delegated, any person has the right to ask for that decision to be reviewed.

A new website information paper gives details of what decisions are subject to review, how reviews are carried out, and how to apply for a review:

Review of Decisions Made under Delegated Authority (ACVM Act)