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News & Views

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New ACVM manager

We are very pleased to welcome our new Manager (ACVM Programmes and Appraisals), Karen Booth. Karen, who led our Registration Review Project, is known to many of you already and needs no introduction. Here are her comments after a few weeks 'on the job':

"After 15 years in the animal health industry, I'm very much enjoying the opportunity to lead the highly skilled and passionate ACVM team. The team has played an integral part in the success of the initiatives implemented in the last two years under the Registration Review. We are continuing to bed these changes in, and work at enhancing the delivery of ACVM registration-related core services.

There has not been too much spare time recently, but I do enjoy being outside walking or running, and keeping muscles strong at the gym. When the Wellington winter ends, I also hope to get back in the garden.

A personal thank you, too, for the emails, messages and greetings, both at the July workshop and in recent weeks. It is much appreciated."

ACVM Annual Fees

Gremlins in the IT system have resulted in some glitches in annual fee invoicing this year. If you have not received an invoice, or if you have received an invoice that you believe is incorrect, please email us as soon as possible: (approvals@mpi.govt.nz)

New Zealand Food Safety
Haumaru Kai Aotearoa
Ministry for Primary Industries
Manatū Ahu Matua

Agricultural chemical 'date of manufacture' label requirement

All agricultural chemicals must have the date of manufacture and the batch number clearly and legibly marked on the product and this information must remain legible for the usable life of the product. If acronyms are used, the meaning should be clearly understood by the user, e.g. DOM is commonly understood to be Date of Manufacture.

Consumer information
In order to manage shelf-life, the product must also have sufficient information on the label for the consumer. For some products with a shelf-life of under two years, or for some products with a shelf-life of two years or more if degradation may pose a significant issue, an expiry date is required and this will be included in the approved label content requirements along with Date of Manufacture and batch number. The expiry, which can be shortened to EXP, must be marked on the label as the date (month and year) after which the product should not be used.

Condition 108
Many agricultural chemical products with an approved shelf-life of two years or over are registered with Condition 108:

"The registrant must provide sufficient consumer advice about the ongoing stability of the product for use if requested by any purchaser of the product. The registrant must withdraw the product from the market place where evidence shows it is no longer capable of meeting its expiry specifications prior to its use, when stored in line with the manufacturer's recommendations."

If Condition 108 is assigned to your product (check your Registration Certificate for conditions), you are still required to include the date of manufacture and batch number.

The next labelling guide update will clarify this requirement.

ACVM 101 Workshops for Registrants, Consultants, New Zealand Agents and Data Assessors

MPI has received feedback and requests for a workshop tailored for parties who are new to the sector, have new staff, or would value an opportunity to upskill in aspects of ACVM and registering trade name products.

In response, we will be holding two 'ACVM 101' Workshops:
1. Wellington on Thursday, 11 October (venue to be confirmed)
2. Auckland on Thursday, 18 October (venue to be confirmed)

These will be one day workshops focussed on the registration process, and MPI's expectations of registrants. The content will be tailored for people with minimal experience in preparing and submitting ACVM applications.

To see details, the draft agenda and to register, go to:
https://www.eventbrite.com/e/acvm-101-workshop-wellington-tickets-49965169166 - Wellington
https://www.eventbrite.com/e/acvm-101-workshop-auckland-tickets-49968381775 - Auckland

FYI

Are you using the currently approved label?

We have recently become aware that after a label change is approved, some registered products have not been updated to the new label content for a prolonged length of time. MPI expects that labels approved should be updated in product inventory in a timely manner, particularly if label changes involve changes in the ACVM regulatory content.

While the ACVM team has not specified timeframes for label changes to occur, we expect that registrants will, as part of good product stewardship, ensure these changes are made when a new print run of labels is needed. If a change has been made that includes a new regulatory statement or significant change in the approved claims, then this change should be made as soon as possible. In relation to this, an audit to look into the labelling of products is planned for the near future.

Heads up: class determinations

We are revising the class determination form and guideline so that we can capture the previously assessed products versus the new class determination applications and their active ingredients. This will improve efficiency in providing class determination advice to applicants.

Diethanolamine

The ACVM team has recently been made aware of a matter raised overseas concerning veterinary medicines containing diethanolamine as an excipient. The issue has been triggered by a recent European Medicines Agency (EMA) evaluation that has concluded that diethanolamine may pose a food safety risk with respect to residues in food-producing animals. There are currently both agricultural chemical and veterinary medicine trade name products registered for use in New Zealand on food-producing animals and crops.

The team is working with MPI toxicologists to review the EMA's decision, and all available information and data, to characterise the risk in the context of New Zealand's registered trade name products and the potential risk associated with diethanolamine residues.

NZPPS Conference

Bruce Nalder, Sarah Lester and Evan Brenton-Rule, who attended the New Zealand Plant Protection Society (NZPPS) annual conference in Nelson from 14 - 16 August, had this to say about the event:

"There were interesting oral presentations and posters on all aspects of plant protection, including biology of weeds, invertebrate pests, pathogens and beneficial organisms. Information also covered methods for modifying their effects from pre-border evaluation of biosecurity risks and eradication of newly-established invaders to the management and control of well-established weeds, pests and diseases of pasture, arable and horticultural crops, and conservation.

This was a great opportunity for us to keep up with current practice and research, as well as connect with researchers and industry groups."

NZPPS annual conference, Nelson, August 2018

Chemistry and Manufacture of Veterinary Medicines (Chemical)

After multiple requests from industry, the submissions close date for the second round of consultation on the draft guidance document Chemistry and Manufacture of Veterinary Medicines (Chemical) was extended to 14 September. Ten submissions were received from registrants and industry representatives on the content of the document and its restructure.

Comments

Most submissions commented positively on the restructure and additional detail of the document, stating that the change will be helpful in generating chemistry and manufacturing dossiers going forward. They also supported the new self-assessable changes, and the ability to deviate from the guidance with case-specific technical arguments and/or alternative data.

MPI response

We are working through all comments and considering changes to the final document. We will address queries and concerns raised by each submitter with formal responses. We note that some comments around specific content in the document may be better addressed by case-specific deviations with technical discussion rather than a change to the guidance itself, but we are considering each submission carefully to be sure that the detail of the guidance is as practical as possible for most registrants while still effectively managing the risks.

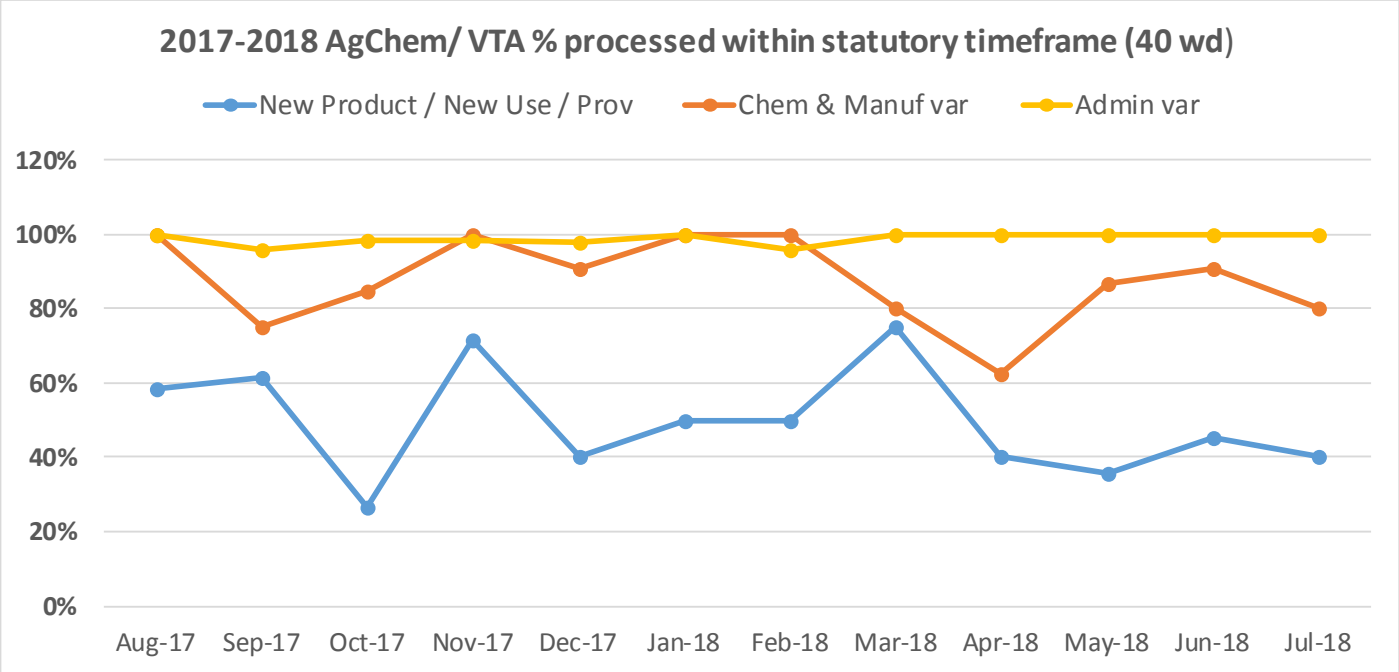
Chemistry and Manufacture of Veterinary Medicines (Biological)

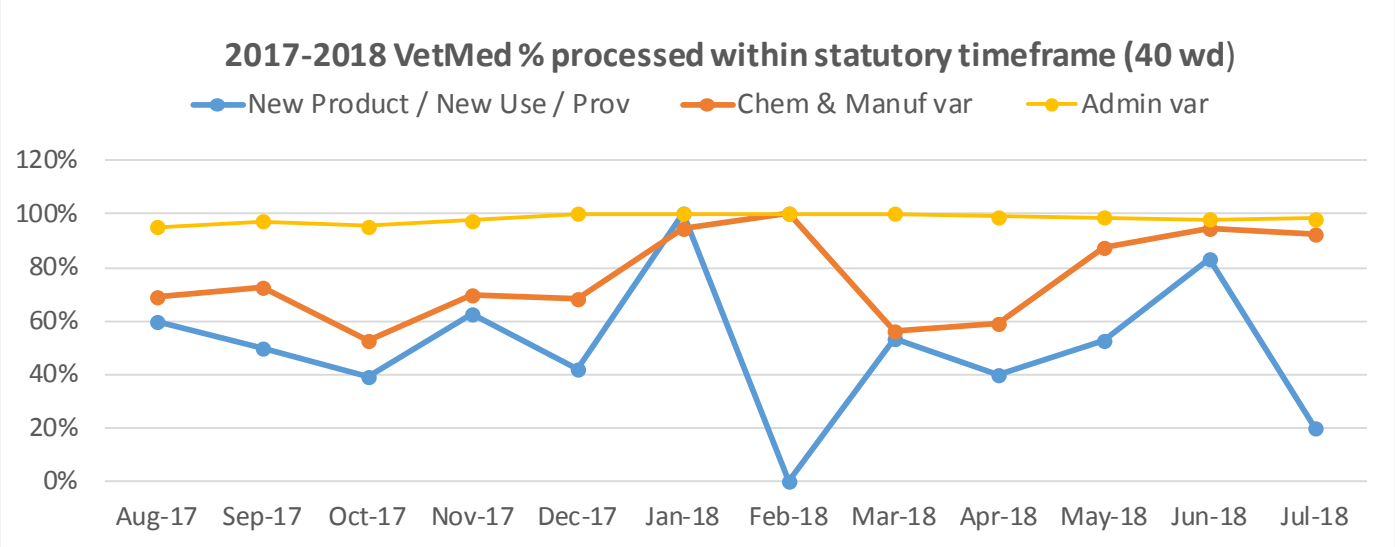
Once the guidance document for the chemical-based veterinary medicines has been finalised, we will begin another round of consultation on the biological-based veterinary medicine guidance document.

Application Performance Statistics

Timeframes for new product and new use applications are currently at 60-80 working days because of lower than normal staffing levels (due to leave and conferences) in the last two months. Twenty-four agricultural chemical and 13 veterinary medicine applications (excluding those pending EPA approval) are affected. Please note these timeframes when planning post-approval activities for new product and new use applications.

Performance continues to be high for the administrative and manufacturing change applications -- 99% of administrative and 91% of manufacturing applications are completed within 40 working days.





July workshop feedback

Following the ACVM workshop in July, participants were invited to complete a Survey Monkey evaluation of the day.

The first half of the survey dealt with rating the organisation and content of the workshop.

Overall, how would you rate the workshop?

Excellent	19%
Very good	53%
Good	22%
Fair	3%
Poor	3%

How organised was the event?

Extremely organised	22%
Very organised	78%

Prior to the event, how much of the information that you needed did you get?

All of the information	47%
Most of the information	50%
Some of the information	3%

Was the workshop length too long, too short, or about right?

Too long	3%
Too short	5%
About right	92%

How informative were the topics presented at the workshop?

Extremely informative	8%
Very informative	58%
Somewhat informative	28%
Not so informative	5%

How relevant was the content of the presentations to you?

Extremely relevant	11%
Very relevant	72%
Somewhat relevant	17%

The rest of the survey was open-ended:

What did you like about the workshop?

(most frequent responses)

- opportunity to meet and interact with so many members of the ACVM team
- professional presentatations
- open discussion
- good organisation and timing (following Agcarm).

What did you dislike about the workshop?

(most frequent responses)

- room too small
- cramped, uncomfortable table arrangement
- acronyms and jargon
- not enough international updates.

Is there anything else you'd like to share about the workshop?

(random selection of responses)

- agenda not available early enough
- valuable tool, keep on having them
- good to see ACVM working closely with Biosecurity
- reading presentation slides out loud isn't a workshop
- may be worthwhile to organise a bus to the airport at the end of the day.

What topics would you like to see covered at future ACVM workshops?

There were too many suggestions to list. These ranged from discussion of a globally harmonised regulatory system to the role of biochemicals to more about the actual assessment process.

Our thanks to all who participated in the workshop and to those who took the time to respond to the survey.

All of the feedback will be considered as we plan future workshops.

ACVM team update

Agricultural Chemicals Senior Adviser **Joy O'Connor** has been on parental leave since last October. For the past few months, we have been fortunate to have **Charmaine Rickerby** filling in for Joy. Charmaine is a chemist with chemistry, manufacturing and regulatory expertise in pharmaceutical and biological products – most recently working at MSD as a Regulatory Affairs specialist in the veterinary medicines field.

Joy is moving to Gisborne and will not rejoin the team when her parental leave finishes (31 October 2018) We will all miss her--Joy's passion and humour, to say nothing of her expertise and efficiency, has made her a key part of the team for eight years. We wish her all the best!

We will start the recruiting process for the Adviser Agricultural Chemicals permanent position soon.

international meetings

OECD Working Group on Pesticides (WGP)

Warren Hughes attended the 33rd meeting of the WGP in Paris in mid-June 2018. The meeting agreed to progress the illegal trade of pesticides OECD Council Recommendation. This will include a best practice guidance for regulators in this area.

The one day seminar on biopesticides discussed tests methods for micro-organisms and ways to improve the regulatory requirements and prepare a list of new or amended test guidelines.

Of the updates from the various expert working groups, the Residue Chemistry Expert Group is expected to initiate work on the update of Test Guideline 509 (Crop Field Trials) and on the development of a guidance document related to residues in honey soon.

Finally, the WGP appointed Warren Hughes as Chair of the WGP for the next two years.

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)

The 36th meeting of VICH was held in Bruges, Belgium, in late June 2018. **Allan Kinsella** and **Warren Hughes** from MPI attended. Items of interest include:

- New Zealand's proposal to move from a 9 month to a 12 month schedule was agreed to by the Committee and will begin in 2020.
- The VICH 6 Conference will be held in Cape Town, South Africa, in late February 2019. The website for the conference is: https://vich6.co.za/.
- At the VICH Outreach Forum (for countries not part of VICH) some of the participants outlined their regulatory systems, and there were presentations on medicated feeds and bioequivalence.

Updates on guidelines documents were:

- Stability: Climatic Zones III and IV - Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV is out for public consultation until the end of December 2018.
- Residues in Honey - Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Species: Study Design Recommendations for Residue Studies in Honey for establishing MRLs and Withdrawal Periods has been finalised and will be implemented next year.

Opportunity in ACVM Audit Team

Christian Morales, one of our Good Manufacturing Practice (GMP) auditors, has left MPI. While we are sad to say farewell to Christian, he is embarking on a fantastic opportunity in the human health industry, bringing innovative products to market. This is an area Christian is passionate about and it will bring interesting challenges for him. We thank Christian for his work in the GMP team, and his contributions to the wider ACVM team over the last (almost) two years, and wish him well for the future.

We want to fill this vacancy as soon as possible. If you or someone you know might be interested in the role, see details on our MPI careers site: https://careers.mpi.govt.nz/jobs/MPI18-1355427

If you have any questions about the role, please contact Karen Booth or Holly Jeboult-Jones.

Closing date is Sunday, 30 September.

NEW TEMPLATE

Dairy Exception Report Template

We have finalised a draft Dairy Exception Report Template document, which is to be used as a guidance document for industry to assist in providing us vital information in situations where an event has put product at serious food safety risk.

This template was designed to provide businesses with a clear expectation of what information we require and in what timeframes we require it. Having the information provided in this format allows us to identify and isolate potentially affected product a timely manner.

The use of this template will avoid situations where we need to go back and forth requesting information, which inevitably slows down the process. (Businesses are able to use their own document templates as long as all the same information is provided.)

The document is now with industry for consultation and will be available for use later in the year.

Food & Live Animal Assurance Team Update

The last three months have seen several staff changes within the Team.

We welcomed back **Michelle Boston** from her year of maternity leave. This meant we said goodbye to **Steve Collinson** who was seconded from the Compliance Team for the year to fill her position. Steve has returned to the Compliance Team and we wish him well in his new role as a Senior Compliance Officer.

We also farewelled **Adeline Langlet** who had been an Adviser with the team for a number of years. Adeline's amazing skills with spreadsheets will be sorely missed, although we are sure she is going to love her new role as an Intelligence Analyst where she will be able to put her skills to good use.

Filling Adeline's role is **Nissy George**. Nissy is a veterinarian who has moved to MPI from Technical Officer roles at Open Country Dairy and Fonterra.

Happy Spring!