Sept 2019

News & Views

ISSN 2538-1059

In this issue...

FRSP survey results

The Food Residues Survey Programme (FRSP), undertaken by the Chemical and Microbiological Assurance (CMA) team of New Zealand Food Safety's Assurance Directorate, conducted an agrichemical residues survey in New Zealand from 2017 to 2019. (See details of FRSP surveys here.)

OPC residues

The results of the 2017 to 2019 survey indicated six of the ten plant food types sampled had residues of organophosphates and carbamates (OPCs) found at detectable levels. Of those, ten individual samples had diazinon, methamidophos and/or acephate residues that exceeded the maximum residues levels (MRLs) under the MRL Food Notice and/or the default MRL of 0.1 mg/kg. (Note that while MRLs were exceeded, food safety assessments were also conducted on those samples and no food safety concerns were identified.)

Off-label applications

When FRSP contacted the associated growers about their spray practices, they found that the majority of the detections were due to off-label applications of registered products. This is a concern as off-label use of these three OPCs has been restricted since the ACVM team's reassessment of OPCs in 2015.

Growers unaware of restrictions

In follow-ups with growers, the majority indicated that they were not aware of this restriction. The survey also highlights the reliance of many growers on OPC products for pest control.

Request to OPC product registrants

Please ensure your labels are up-to-date and that your distributors and retailers are well informed about the registration conditions.

We are exploring options on how to better inform growers about restrictions on OPC agricultural chemicals to ensure compliance with regulatory requirements. This would include what roles registrants, distributors, and producer sectors can play to better inform growers of such restrictions. We would welcome any views or suggestion on what New Zealand Food Safety and other sectors could do in this area. If you have any suggestions, please send your email to: foodassuranceprogrammes@mpi.govt.nz

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

Advertising of Agricultural Compounds

The current ACVM advertising guidance document, which provides guidance on what is acceptable for advertising versus information transfer and wording to use in advertisements for registered trade name products, is more than six years old.

Since it was written, there have been many changes affecting advertising:

- a significant growth in advertising in social media, electronic newsletters and other digital platforms
- a recent change in the advertising requirements for restricted veterinary medicine antibiotics
- increased number of queries to MPI on the advertising requirements for agricultural compounds exempt from registration.

In light of the above, MPI considers that the advertising guidance document needs a significant refresh. There will be an opportunity for stakeholders to comment on a revised draft.

If you have any questions on this, please contact Warren Hughes (warren.hughes@mpi.govt.nz).

Public notification of ACVM product recalls

Voluntary and regulator-initiated recalls of ACVM products (both registered and exempt) are not uncommon events. As part of the recall process, the supply chain and, in certain cases, end users are notified directly by the registrant/owner of the product.

Regulators overseas publicly notify product recalls:

- APVMA, Australia - https://apvma.gov.au/node/1081
  APVMA publishes both voluntary and compulsory recall notices on its website, and the APVMA Gazette
- FDA, United States - https://www.fda.gov/Safety/Recalls/default.htm
- Veterinary Medicines Directorate, UK – published in MAVIS, e.g. https://www.gov.uk/government/publications/mavis-hub-edition-111/mavis-hub-111#product-news

MPI will improve transparency of New Zealand ACVM product recalls (both voluntary and mandatory) by publishing the relevant recall information on the MPI website – ACVM home page – ACVM alerts and notifications. In the food space, MPI also publicly notifies food recalls on its Facebook page. However, we are not proposing to use social media for ACVM recall notifications at this time.

The information to be published in the notification will include:

- Date
- Name of company
- Product trade name (ACVM registration number, if applicable)
- Batch numbers / Date of manufacture / Expiry date, if applicable
- Reason for recall
- Risk assessment summary
- Advice to people in possession of the product concerned.

This change will be effective from 1 November 2019.

new credit card payment system

The credit card payment option on our application forms has been changed to provide more privacy and security to applicants. From now on, when you choose to pay by credit card, you will be directed to a secure Westpac payments portal.

FYI

Cannabidiol (CBD) and hemp-based products

With the changes to the status of cannabidiol (CBD) from a controlled drug to a prescription-only human medicine under the Medicines Act, there has been increased interest in the use of hemp and CBD as veterinary medicines. Please be aware that all hemp-based products, including CBD products, intended for animal use or consumption must be registered as veterinary medicines before they can be imported, sold, or used in New Zealand animals.

There are currently no hemp-based veterinary medicines registered under the ACVM Act, and only one cannabis-based product consented under the Medicines Act. Any unconsented CBD product being legally sold for human medicine under section 29 of the Medicines Act cannot legally be sold to veterinarians. Veterinarians wanting to authorise hemp-based products for patients under their direct care must get an MPI Special Circumstances Approval.

MRL notice

The amended Food Notice: Maximum Residue Levels for Agricultural Compounds came into effect on 30 August 2019. You can access the document and get more information about MRLs on our website: https://www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/maximum-residue-levels-for-agricultural-compounds/

Antibiotic sales reports

The **2017 Antibiotic Sales Report** is due for publication in October 2019. Thank you to those people who submitted feedback on the draft report following the consultation round, which ended in August. Feedback is essential to ensure the information published has context around the data and to help MPI establish why certain trends have occurred.

Data for the **2018 Antibiotic Sales Report** is currently being readjusted following information from some registrants that the data they submitted was incorrect. We hope to have a draft 2018 report out for consultation during the first quarter of 2020.

Sales data for 2019 is due for submission to MPI by 31 March 2020. We will send registrants a request for this data in early January next year.

upcoming workshops

Chemistry and manufacturing guidance workshop

The new Guidance Document: Chemistry and Manufacturing of Veterinary Medicines (Chemical) is currently being completed after its third round of consultation. Because this revised guideline is much more detailed and comprehensive than the current ACVM Registration Standard and Guideline for the Chemistry of Veterinary Medicines, the team will hold a workshop in Wellington on Tuesday, 1 October, at TSB House (Level 1), 147 Lambton Quay, Wellington.

The Chemistry and Manufacturing workshop will cover:

- A walk through the document and the changes from the current Standard and Guideline
- Implementation of the new Guidance, what will be expected in dossiers, and data assessment
- Discussion and feedback for the drafting of the Guidance Document: Chemistry and Manufacturing of Veterinary Medicines (Biological)
- Open Q+A around chemistry and manufacturing topics.

Register here: https://www.eventbrite.com.au/e/new-guidance-document-chemistry-and-manufacturing-of-veterinary-medicines-workshop-tickets-70841319293

Registration closes 24 September at 5pm.

Please note tea and coffee will be provided but you will have to organise your own lunch. We have limited spaces, so register on time to avoid disappointment.

Data assessors workshop

The ACVM team will hold a workshop for data assessors on Friday, 18 October (9am - 4pm) at TSB House, 147 Lambton Quay, Wellington. This is a forum for data assessors (listed or otherwise) to discuss topics of interest with ACVM staff. Morning tea, lunch and afternoon tea will be provided. There will be a charge to cover costs.

In preparation for this event, please:

- Email topics or issues that you would like covered in the workshop to approvals@mpi.govt.nz as soon as possible
- Provide comment on the frequency and quality of feedback you have been receiving on your DARs from MPI. (Please note: provisionally listed assessors should be expecting more feedback than fully listed ones.)

Register here: https://www.eventbrite.com.au/e/data-assessor-workshop-2019-tickets-70860420425

Registration closes 4 October 2019.

An agenda will be sent closer to the time of the workshop.

call for expressions of interest for ACVM 101 workshop

Two workshops for those with minimal experience in submitting ACVM applications were held in 2018. Feedback was very positive from those who attended, and there have been some queries about another ACVM 101 workshop.

To register your interest, please email with the subject heading 'ACVM 101 Workshop' to approvals@mpi.govt.nz . If there are enough numbers, we will run another workshop.

Introducing...

Sara Ashby
Adviser, Veterinary Medicines
ACVM Programmes & Appraisals

"I'm a Massey graduate and I've spent the last few years working as both a large animal and small animal vet – first in Otaki where there was a distinct rural feel, and more recently moving between clinics around the greater Wellington region.

I left clinical practice to take up an exciting new challenge with the ACVM team.

Prior to my veterinary career, I had one in teaching which included stints in London and Abu Dhabi.

I'm really delighted to be settled back in Wellington now, the best little capital in the world!"

Russell Clark
Auditor, Regulatory Programmes

"I joined the ACVM team in early August 2019. Prior to this I worked for 21 years in the pharmaceutical industry in both Australia and New Zealand in analytical chemistry, validation, and research and development.

I graduated with a Ph.D in organic chemistry from the University of Auckland in 1998 and have had a previous taste of working for a government organisation when I was the Team Leader of Pharmaceuticals at ESR (Institute of Environmental Science and Research) from 2011 to 2013.

In my spare time I am an avid cricket follower as well as someone who enjoys bush walking. I am also a keen student of Indian cuisine."

Kate Jolly
Adviser, Approvals Operations

"I have worked at MPI in my university holidays (I have been studying an Applied Economics degree at Massey University) since leaving school at the end of 2016.

I started as a support officer but moved into the Approvals Operations team at the end of 2017, and I started a full-time role in July 2019. I have worked under the Animal Products Act and the Wine Act predominantly but have now also started working under the ACVM Act.

In my spare time I enjoy spending time with friends and family, and taking my dog out for walks."

Feedback on Winter Workshop

Thank you to the 40 workshop participants who completed the Survey Monkey evaluation questionnaire. The results were nearly all positive with many comments about good interaction and appreciation for having all the ACVM staff there for part of the day. Suggestions for improvements will be taken on board. (Not sure that we can stop the Wellington fog, though!)

There were 13 ideas for future workshops and two of them are scheduled for October (see page 4).

Pesticides for pathogens of honeybees

A range of pathogens affect honey bees in New Zealand. Management of these pathogens can be achieved through good beekeeping practices and via the application of pesticides.

Registration required?
Pesticide products sold and used to treat honeybee diseases require registration under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act). However, if a beekeeper prepares their own compound for use on their own beehives – such as oxalic acid strips – then registration may not be required.

Own use
The ACVM Act and related legislation does allow users' own use of agricultural compounds (including varroacides) on their own land (in this case beehives) provided they comply with all the rules. There are strict requirements around own use in Schedule 2 of the ACVM (Exemptions & Prohibited Substances) Regulations.

The compound must still be 'fit for purpose' under these Regulations. The compound or product must not be sold. It is the responsibility of the person using the compound to ensure its use complies with the fit for purpose requirement, and any other requirements under these Regulations. Part of this responsibility is that users have a good understanding of the compound and measures in place to ensure it remains fit for purpose when used. If this responsibility cannot be complied with, then the compound should not be used.

More guidance on own use for beekeepers will be published on the ACVM website soon.

Slaughter intervals for leaf-plucking

Recently the ACVM team has received a number of queries regarding slaughter intervals for leaf plucking, which is a practice that is becoming more common. Our advice is the 6 month default slaughter period applies (i.e. a 6 month period on "clean-feed" before livestock is sent to slaughter) unless the active ingredient was part of the NZ Winegrowers study that indicated a 2 month slaughter period was acceptable. The notable exceptions are the chlorothalonil products, which should not be used where leaf-plucking is expected.

If the active ingredient was not included in the NZ Winegrowers study, then no advice can be given on a slaughter interval other than the default 6 month slaughter period applies (unless there is the possibility that the compound or a metabolite is very persistent in animal tissue, then the 6 month default may also be inappropriate). To reduce the slaughter interval to the 2 month period, a registrant can apply for a variation to their registration and supply the appropriate data (as outlined in our residue guidance document for agricultural chemicals). This is then required to be stated on the label.

We recognise that there is a lack of guidance on what information should be stated on the label. This has led to some labels having a statement on the label, while others do not. While lack of a slaughter period on the label means the default of 6 months applies, this may not be clear to some in the industry. Therefore, we will review our requirements in this area.

Finally, note that post-harvest grazing in vineyards and orchards is separate to the above.

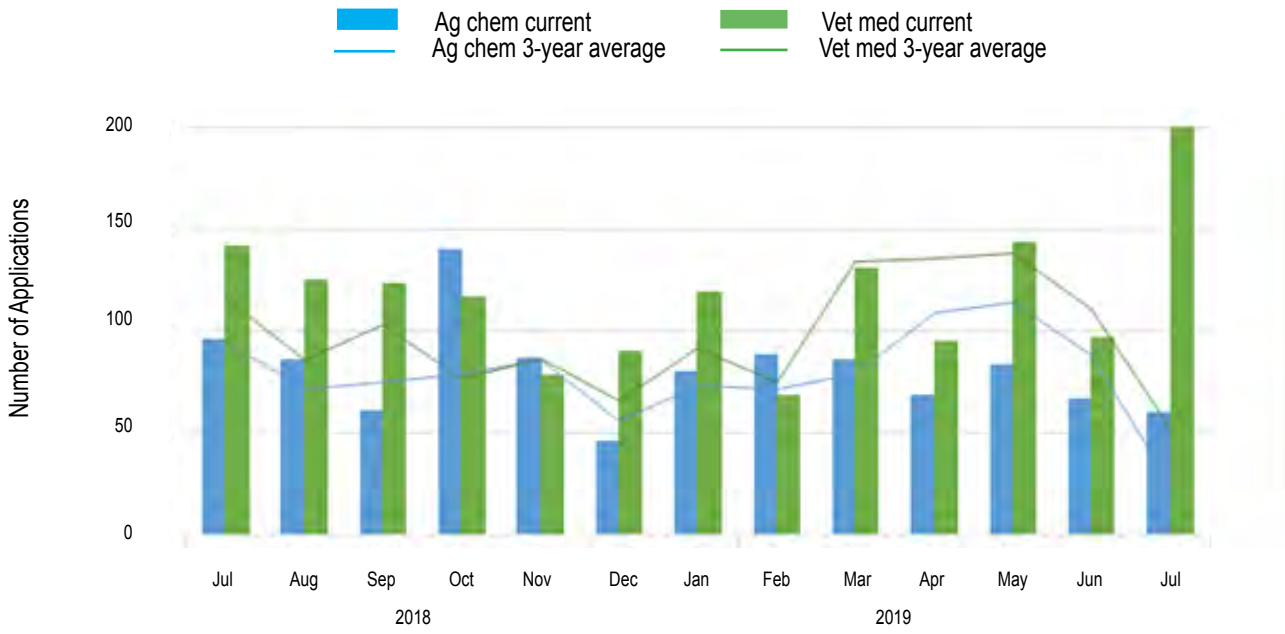
APVMA approvals for active ingredients (agricultural chemicals)

For agricultural chemicals, the ACVM team does not require batch analyses for active ingredients from manufacturing sites that have an Australian Pesticides and Veterinary Medicines Authority (APVMA) approval. However, the APVMA no longer publishes approved Technical Grade Active Constituent manufacturing sites on their website. This means that when you are adding an active ingredient manufacturer that has an APVMA approval, you will now need to provide the APVMA approval to us rather than just the APVMA approval number or a notification. Please make sure that the approval includes the physical manufacturing site address. If this is not possible, a batch analysis from the manufacturing site will be required.

Performance Metrics

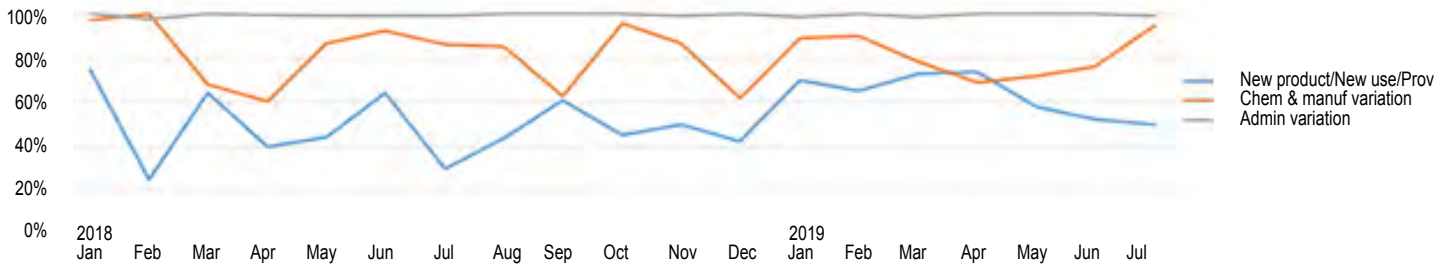
Application volumes are settling to 3-year average levels for veterinary medicines, after higher than average numbers through most of 2018. The spike in July 2019 was the 251 applications from the reassessment of advertising of antibiotic restricted veterinary medicines (RVMs). Agricultural chemical applications remain at or below 3-year average.

Volumes of Applications Received vs 3-Year Trendline



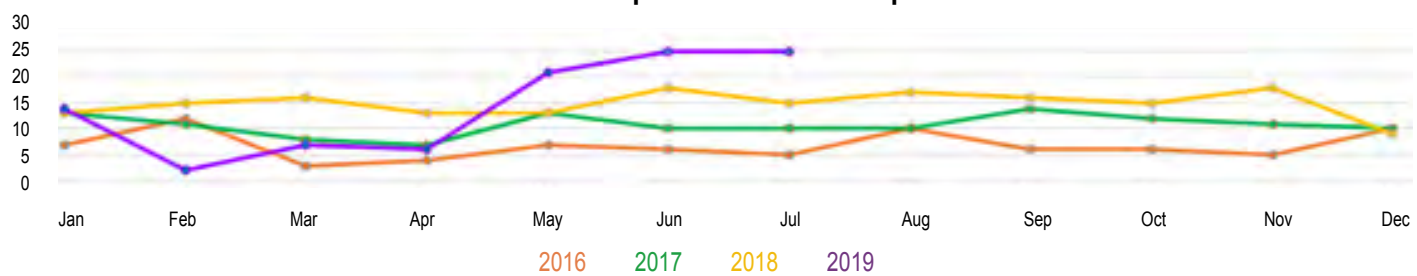
Overall there has been improvement in processing times for chemistry and manufacturing variations (95% processed within 40 working days). Approximately 50% of new product and new use applications were processed within 40 working days.

% ACVM Applications Processed in Statutory Timeframe (40 working days) Jan 2018 - June 2019



There has been significant activity in the compliance area, particularly TradeMe listings of non-compliant products and non-compliant products in the exempt space.

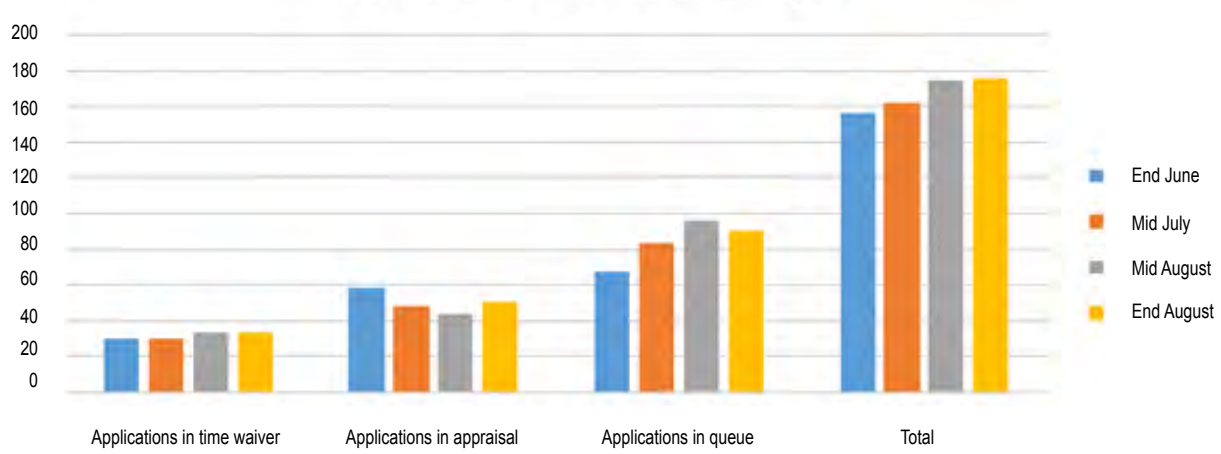
Total Compliance Activities Reported



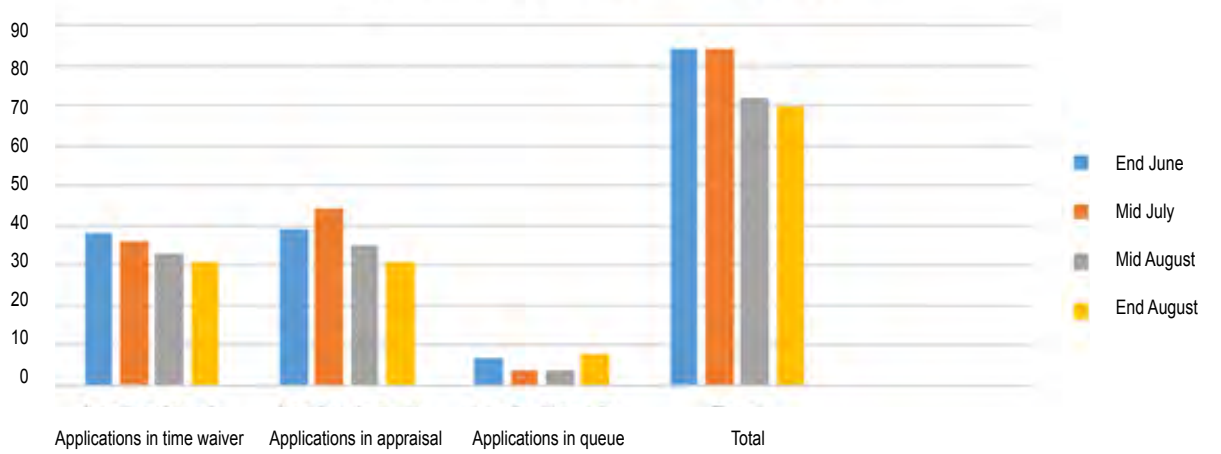
Performance Metrics continued

The veterinary medicine application queue is still large. This backlog is likely to remain for the next quarter as the new Adviser Veterinary Medicines settles in.

Veterinary Medicine Application Status by Date



Agricultural Chemical Application Status by Date



APPLICATION FILES -- HELP!

In our last issue, we requested applicants to provide dossiers/files that are searchable by key word and organised according to our e-files guidance. However, our assessors are still getting applications with up to 200+ individual PDF/Word files for review. If this situation continues, we may have to reject these non-compliant applications that take so much more time to assess.

Please ensure that your applications comply with our e-files guidance (https://www.mpi.govt.nz/dmsdocument/3010-e-files-for-acvm-applications).