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News & Views

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Food Residues Survey Programme

The final report of the Food Residues Survey Programme (FRSP) survey results for 2017-2019 was published on the FRSP webpage in April.

Over the two-year period, 591 samples were collected and analysed for more than 500 agrichemicals and metabolites. The overall rate of compliance, which is greater than 99.9% for the samples tested, is similar to the previous surveys of 2013-2014 and 2015-2016. The samples that were non-compliant were risk assessed for New Zealand consumers' dietary exposure and posed no food safety risks for any age groups.

New Zealand Food Safety has also identified an area for improvement in regards to acephate and methamidophos. To help improve the understanding of organophosphate use to growers, New Zealand Food Safety has co-branded a pictorial poster with Vegetables Research and Innovation. The poster, Guidance on the use of acephate and methamidophos insecticides on vegetable crops, is available on our website.

Calendar

1 June:	*Close of 3rd quarter MRL promulgation proposals (see page 5)*
mid July:	*Public consultation begins for 3rd quarter MRL round*
22 July:	*Winter Workshop cancelled*
1 Sep:	*Close of 4th quarter MRL promulgation proposals*

New Zealand Food Safety
Haumaru Kai Aotearoa

Ministry for Primary Industries
Manatū Ahu Matua

Medicated feeds

The Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 (ACVM Regulations) allow for animal feeds containing therapeutic or pharmacological substances, commonly referred to as 'medicated feeds', to be exempt from registration as a veterinary medicine. This exemption is conditional on the expectation that:

1. The therapeutic or pharmacological substance being added to the feed is a veterinary medicine registered under the ACVM Act.
2. The inclusion of the veterinary medicine is consistent with the indications, use patterns, target species, and conditions of that product's registration.
3. The veterinary medicine will remain adequately distributed throughout the medicated feed and remain efficacious for the feed's shelf life.

This means that the manufacturer of the medicated feed must incorporate the veterinary medicine as per the registered product's approval, and the final medicated feed must be able to be used safely and effectively by the farmer or owner in the approved target species and class.

Labels

The following must be included on the label of every package of animal feed that contains a registered veterinary medicine:

- The name of the registered product incorporated into the medicated feed
- The active ingredient in the registered product incorporated into the medicated feed
- The claim approved for the registered product associated with the dose rate and intended use of the medicated feed (e.g. as an aid in the control of coccidiosis caused by *Eimeria* species in calves)
- Directions for use of the medicated feed, including feeding instructions to provide the approved dose of the veterinary medicine at the approved interval (e.g. once a day, twice a day, continuous feeding) and duration of treatment (e.g. feed for 7 days then switch to a non-medicated feed, feed continuously until weaning)
- All warnings, safety precautions, and contra-indications listed on the veterinary medicine's approved label
- The withholding periods from the approved label
- A use-by date or shelf life of the medicated feed reflecting that listed on the veterinary medicine's approved in-use shelf life, and
- A batch number or other information sufficient to allow medicated feed's date and place of manufacture to be determined.

The manufacturer of the medicated feed must also ensure that the feed is suitable for mixing the veterinary medicine into, and that the final medicated feed is mixed thoroughly and evenly into the feed so that when fed to the target animal, the correct dose is being administered. The manufacturer is also expected to keep records of their documented manufacturing system in accordance with Regulation 9 of the ACVM Regulations, which include all points specified in that regulation for both the feed and the veterinary medicine incorporated into the feed for each batch of medicated feed produced.

Life and Business at Alert Level1

- The ACVM team began working remotely on 23 March 2020, three days before the Alert Level 4 lockdown. The systems, tools and processes we had in place supported this move, and the team has been able to respond to industry requests and continue to deliver core services. Now that New Zealand is at Alert Level 1, we are moving back to TSB House, Wellington, but we will continue to engage with industry using virtual meetings.

- If you expect or anticipate any supply issues due to Covid-19, please let us know as soon as possible.

FYI

Magnesium supplements

Further to the article in the April issue of *News and Views*, guidance on magnesium supplementation in dairy cows is now available on our website.

Labelling agricultural chemicals

The revised guidance document Labelling Agricultural Chemicals is available on our website and should be used for developing or updating labels from now on.

Ag chem chemistry and manufacturing

The Agricultural Chemicals Chemistry and Manufacturing guidance document is out for consultation. Please check here for more information. The closing date is 30 July 2020.

Vet med chemistry and manufacturing

The new guidance document Chemistry and Manufacture of Veterinary Medicines (Chemical) is now available on our website. Since its release, there have been two minor amendments to the Guidance. The first was the correction of an error in section 7.4.4, which said "active ingredient" where it should have said "critical excipient". The second, and more significant change, was the addition of a point to specifically clarify that release to market entities do not require evidence of GMP compliance. Although this is not different than what was stated in the Guidance on its release, this point was added to ensure this point is clear.

Registrant comments on flow-on changes to the content of the product datasheets and the veterinary medicine variation application form from the revision of this guidance are being reviewed prior to finalising the revised PDS and application form.

The first draft of the Chemistry and Manufacture of Veterinary Medicines (Biological) guidance is being finalised for consultation, and should be released for review in the next 4-6 weeks.

ACVM Regulatory Programmes – Compliance Activities

During the Covid-19 lockdown it was generally business as usual for the Regulatory Programmes team. However, actioning some non-compliance events were delayed during levels 3 and 4 while companies were either not operating or operating in limited capacity and would have been unable to take action to bring their product(s) into compliance.

Complaints
During April and May the Regulatory Programmes team received 20 complaints regarding unregistered ACVM products. The majority of these complaints related to exempt products that were non-compliant with the conditions of exemption or products being sold that should be registered.

We received two complaints regarding ACVM registered products.

- Everyone is reminded that advertising unapproved label claims is a breach of the conditions of registration (condition 66).
- The full registered trade name must always be used when advertising your product. This avoids potential compliance issues and avoids confusion with other registered products that may have similar trade names.

For more clarification, please read Advertising guidelines for products registered under the ACVM Act.

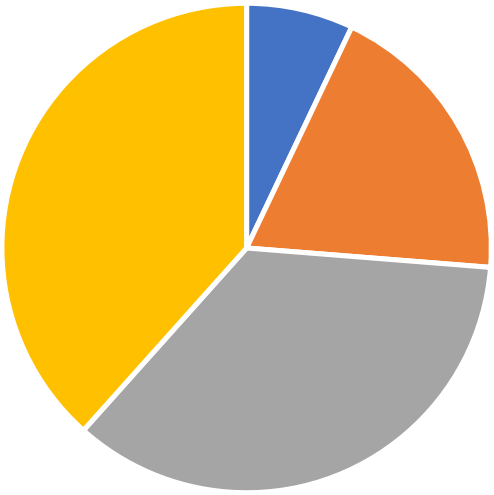
We also received eight notifications relating to non-conforming batches of ACVM registered product released or yet to be released to the market.

Status of non-compliance events
Of the 99 non-compliance events reported so far in 2020, 35% are considered appropriately actioned and are now closed. Note that one non-compliance event may include multiple non-compliant products sold and/or advertised by the same company, so some non-compliance events can take more time to investigate, action and rectify.

Watch this space….
An online reporting tool is being created to make it easier to report products that may not be compliant.
We are also working on a form and guidance to make it simpler for registrants to report a non-conformance regarding their own product.

We will let you know when the online complaints reporting tool and the non-conformance reporting form are live.

Reported Events of Non-Compliance 2020
1 January - 2 June = 99 events



7 pending external response
19 pending internal review/action
38 received, queued for action
35 closed

Compliance Related Activities

Examples of the types of non-compliance events reported during 2020

- *The most common complaints regarding **unregistered** ACVM products received so far are unregistered products making claims to treat, prevent, control or cure a disease characterised by pain or distress in animals.*
- *The most common complaints regarding **registered** ACVM products received so far are:*

  decanting and selling of registered products into unapproved packaging and pack sizes

  registered products being sold with unapproved product labels

  registrants advertising unapproved label claims
- *We are working with Trade-Me to remove non-compliant ACVM products from sale.*

Reassessments

Tranche 1 antimicrobial reassessments

The June deadline for submission of the Tranche 1 reassessments has now passed, and applications are currently being reviewed for formal receipt. The next step in the process is public notification of the reassessments in the New Zealand Gazette, grouped by active ingredient and/or product registrant. The public notification period is 30 days, after which applications will enter the statutory regulatory timeframe of 40 working days.

MRL promulgation proposals resulting from the reassessment appraisals will be included in the September round of promulgation proposals if their assessments have concluded, or in the January 2021 promulgation round if assessments are not complete prior to 1 September.

The Tranche 2 review report will be finalised and released for review in the coming weeks.

Ionophore reassessment update

In 2018, registrants were asked to provide applications to reassess products containing the ionophore active ingredients decoquinate, lasalocid, and monensin. These applications were requested based on new information that the New Zealand MRLs assigned to these compounds were not sufficient to manage the residue and trade risks associated with their use. Due to a number of other competing priorities, this work has since stalled.

To move this work forward, the reassessment plan for these compounds will be reinitiated with a MRL review similar to that undertaken for the Tranche 1 AMR reassessments. In this review, the residue profiles, international MRLs, and New Zealand trade risk will be assessed at the compound level based on historic information on file with ACVM and publicly available data to determine sets of provisional MRLs. These will then be presented, with individual evaluations of their product-specific impacts on withholding periods, to affected registrants for comment. At that stage, registrants will be given a time frame for submission of their comments and any updates to application documents prior to formal receipt and public notification of the applications.

As is the case now, registrants will still be permitted to submit variation applications as required until the point of formal receipt of the reassessment applications. This review work is expected to be completed in the next 6-12 months.

MRL promulgation update

The third 2020 MRL promulgation proposal round closed on 1 June, and the team is now in the process of drafting proposals for public consultation. As was the case for the first two rounds this year, the consultation document is expected to be released in approximately four weeks from round closure (early July). The fourth and final round of 2020 MRL promulgation proposals will close on 1 September, with a goal of public consultation in early October.

Starting in January next year, the schedule for promulgations will be adjusted slightly to allow for even, three month intervals between round closures. These close dates will be 1 January, 1 April, 1 July, and 1 October. Any requests for promulgations received and ready to progress before the round close date will be included in that next round (note: MRLs ready for promulgation between 1 September 2020 and 1 January 2021 will be included in the 1 January round).

ACVM 101 Handbook

For any questions about registration, from data requirements to post-authorisation, your first point of reference should be the 2018 guideline ACVM 101 Handbook.

Introducing our 4 new Approvals Advisers...

Hannah Cameron
"I am from Scotland and I came to New Zealand last year after traveling for several months following graduation from The University of Edinburgh with a Bachelor of Science (hons) in Ecological and Environmental Science.

Before I joined the Approvals team I was a support officer in the Planning and Support Services team in Agriculture and Investment Services in MPI. In my current role as an Adviser, I work across the Food, Animal Products and ACVM Acts.

In my spare time I am a keen painter. I enjoy baking and going on adventures."

Brenna Tume
"I graduated from Victoria University of Wellington with my Bachelors in 2018, while I was working abroad in Austin, Texas.

I started at MPI after moving back to New Zealand and I have been in the Approvals team since March 2019, working under the Animal Products and Wine Acts. This year I have started to work under the Food and ACVM Acts as well.

In my spare time I enjoy playing sports and catching up with family and friends."

Marta Teal
"I started working for MPI in January this year after finishing a Bachelor of Science, majoring in Cell and Molecular Bioscience in 2019.

I currently work across the ACVM and Food Acts, and am training to do more under the Animal Products Act. I enjoy long walks and riding my horse on the beach during weekends."

Tim Topham
"Since graduating from Victoria University of Wellington with a Bachelor of Science, majoring in Biotechnology and Cell and Molecular Bioscience, I have mainly worked in a lab role at Eurofins ELS. After deciding that I did not want to pursue a career working in a lab environment, I looked to further my career elsewhere and landed my current role at MPI as an Adviser on the Approvals team. I currently work across the ACVM and Animal Products Acts. As things hopefully begin returning to normal after Covid-19, I will begin training in the Food and Wine Acts.

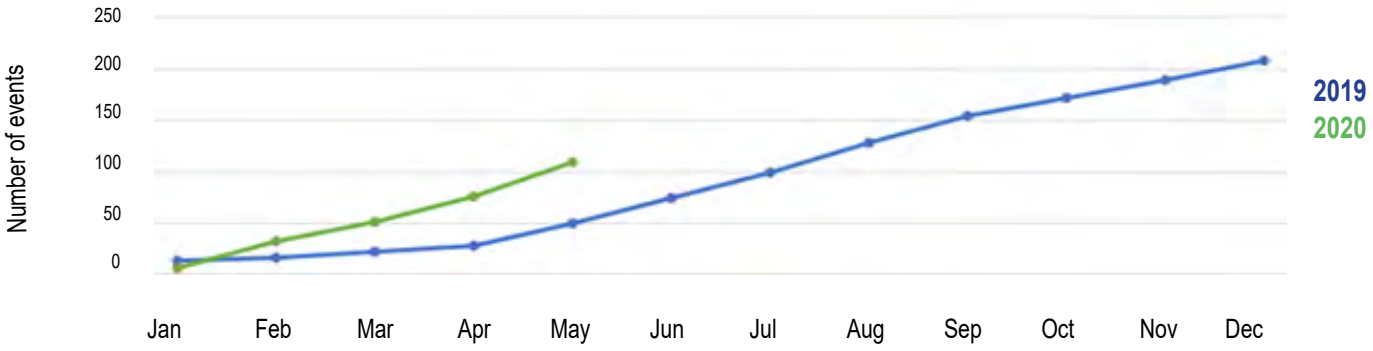
In my spare time, I like to get out in nature for hikes, eat, play sports and keep fit."

Farewell to Sarah de Barr

On 22 May we farewelled Sarah from the team. She has left MPI for a role in industry, and we wish her well. Sarah provided support in the administrative management of the Adverse Event reporting programme, and will be well known to some of you. David Tran will now be managing this function, and adverse event reports can still be reported to ACVM Adverse Event Reporting at ACVM-AdverseEvents@mpi.govt.nz

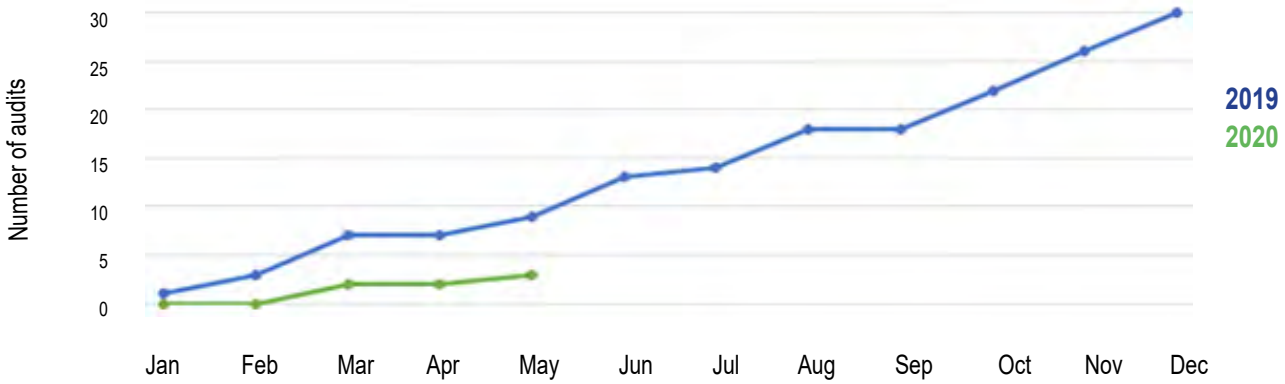
Performance Metrics

Cumulative Annual Compliance Related Activities (also see page 4)
including reported non-compliance events, batch specific variations, rapid alerts and non-conformance reports



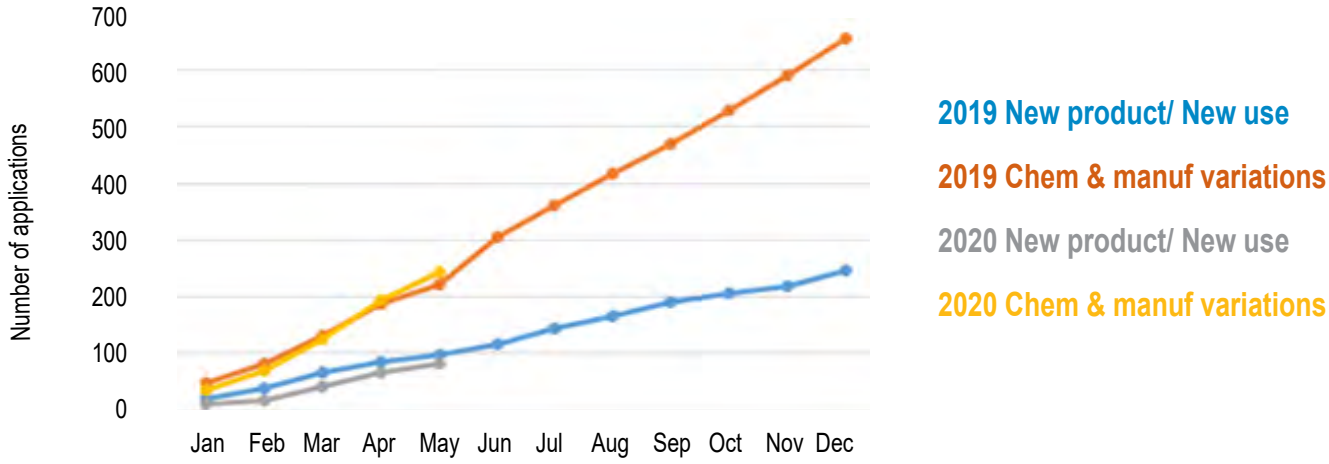
The total for 2020 also includes Batch Specific Variations, which were not included in the previous year's figures.

Cumulative Annual Good Manufacturing Practice (GMP) Site Audits Performed



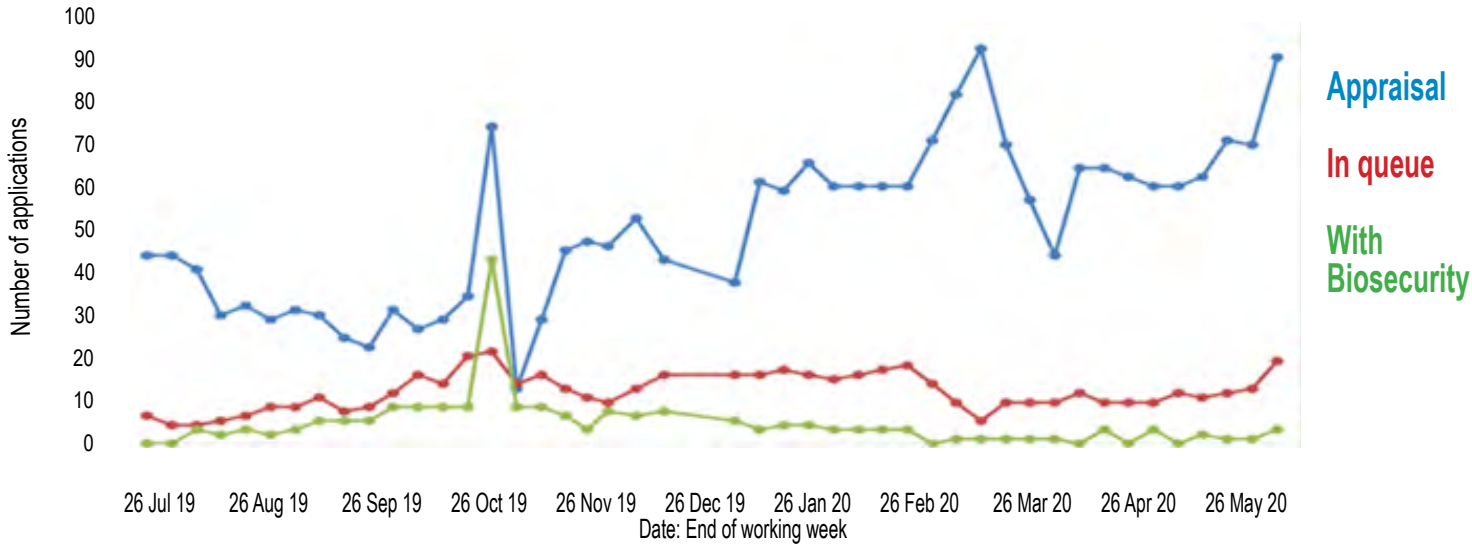
Several audits were delayed during March, April and May. Any audits that were postponed are being rescheduled with a busy few months ahead.

2019 - 2020 ACVM Technical Application Approvals (Cumulative Volumes)



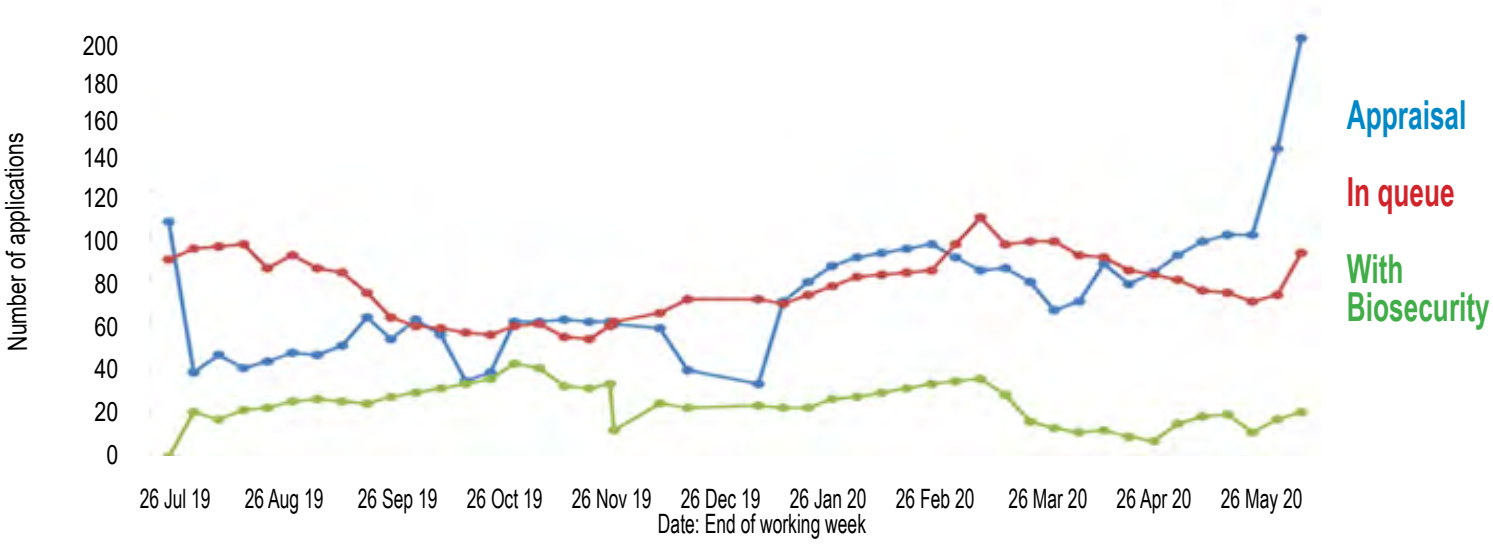
Performance Metrics

Agricultural Chemical Application Status by Date



The AgChem team continues to keep their application queue to a manageable level.

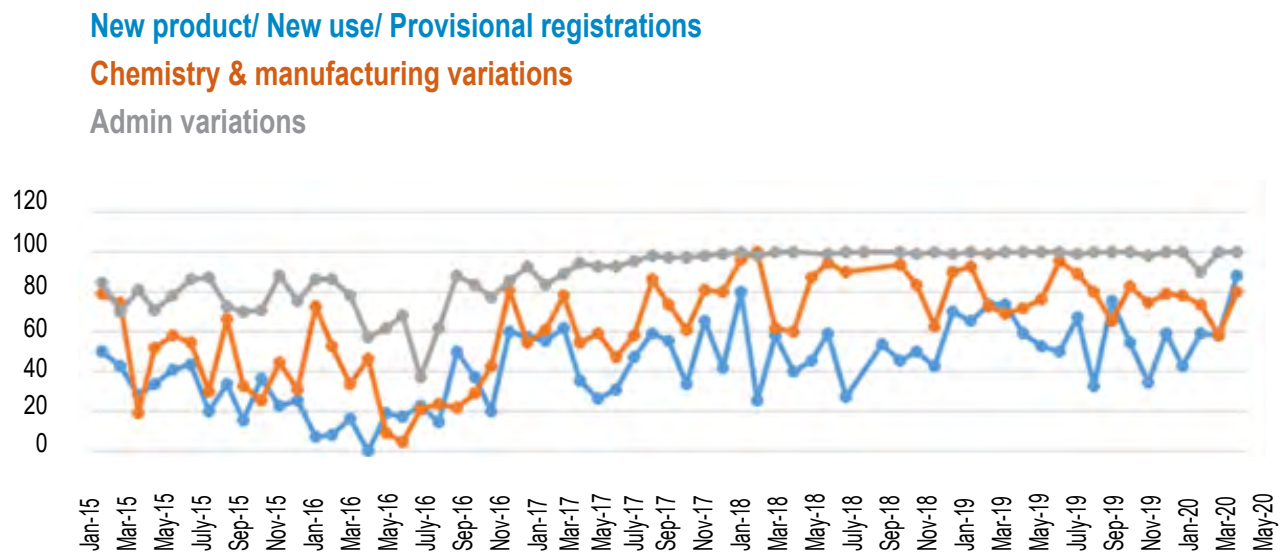
Veterinary Medicine Application Status by Date



There still is significant backlog of Vet Med applications. This is mainly due to being short-staffed in the last year (two vacancies in the vet med team) and steady incoming application volumes. Of the 189 applications in appraisal, 110 are part of the Tranche 1 antibiotic reassessment, and will be managed by the Specialist Adviser Veterinary Medicines. The team has worked hard to decrease the queue from 108 in March 2020 to 79 non-reassessment applications. One Vet Med Adviser vacancy has been filled with a start date of July 2020, and recruiting is ongoing for the second vacancy.

Performance Metrics

2015 - Current
% All ACVM Applications Processed within Statutory Timeframe (40 working days)



data protection clarification

A recent discussion of application submissions and protection of confidential information has identified that there may still be some confusion about what does and does not qualify for protection under Part 6 of the ACVM Act. Please note when compiling information for application submissions for registration, provisional registration, and research approval that the following applies:

- All proprietary data submitted to support a new registration, or new use variation to an existing registration, is eligible for Part 6 protection, and will not be available for cross reference. Publicly available information can be captured if included in the dossiers, but this does not preclude another company from accessing and presenting publicly available information to support their own application.

- Application forms, the product datasheet (PDS), and other documents containing confidential information are eligible for Part 6 protection, but the registrant must identify the documents as information to be protected by listing them in the Identification of Confidential Information for Data Protection form (ACVM 1DP). If not listed in this form, the data and information will still be treated as confidential, but not formally protected under Part 6.

- Data provided to support an application for Biosecurity approval is NOT eligible for Part 6 protection. This is because this information is not submitted for ACVM purposes, and therefore not in scope for protection under the ACVM Act. The Biosecurity approval letter is eligible, however, as this letter is required for ACVM approval and therefore in scope. The Biosecurity approval letter can be listed in the ACVM 1DP form if the registrant feels it contains confidential information to be protected.