Feb 2020

News & Views

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In this issue...

But wait – there's more...

This year we plan to publish *News and Views* bi-monthly instead of quarterly.

We have found that a three months' gap is too long if there is time-sensitive information for you, such as upcoming events that you may want to schedule into your diaries. So, if all goes to plan, 2020 issues will be produced in February, April, June, August, October and December.

This new timeframe is likely to mean shorter, quicker to read publications. We are also introducing a calendar to give you a user-friendly heads-up.

Ideas for articles, questions, and comments are always welcome.

Calendar

25 February:	***ACVM team planning day***
1 March:	***Cut-off for inclusion in 2nd quarter MRL round (see page 4)***
31 March:	***Deadline for submissions on AMR reassessment (see page 3)***
3 April:	***Public consultation ends for 1st quarter MRL round***
22 July:	***Winter Workshop (to be confirmed)***

New Zealand Food Safety
Haumaru Kai Aotearoa

Ministry for Primary Industries
Manatū Ahu Matua

New policy on nil day WHP for agricultural chemicals

From now on, the ACVM team will not accept a nil day withholding period (WHP) for pre-harvest use for agricultural chemicals, including biological products.

Review finding

A review of the current policy by ACVM in consultation with AVMAC found that a nil day WHP is not justified in most instances for pre-harvest use of agricultural chemicals. This finding is on the basis that it is not considered good agricultural practice (GAP) in nearly all circumstances as the need to spray just prior to harvesting will not contribute significantly to the efficacy of a product. Further, it is unlikely to be necessary for a grower to have such flexibility in management of harvesting a crop.

As an aside, from a health and safety perspective, the re-entry periods set by the Environmental Protection Authority (EPA) are normally not set at zero days. Consequently, a minimum of 1 day WHP is considered appropriate for registering any agricultural chemicals, regardless of whether it is conventional or biological-based chemistry.

Incorrect perception

It is important that users have an understanding of what a WHP means. Therefore this change will also assist the general incorrect perception of users that a WHP is primarily for the management of residues and that a nil day WHP indicates zero residues.

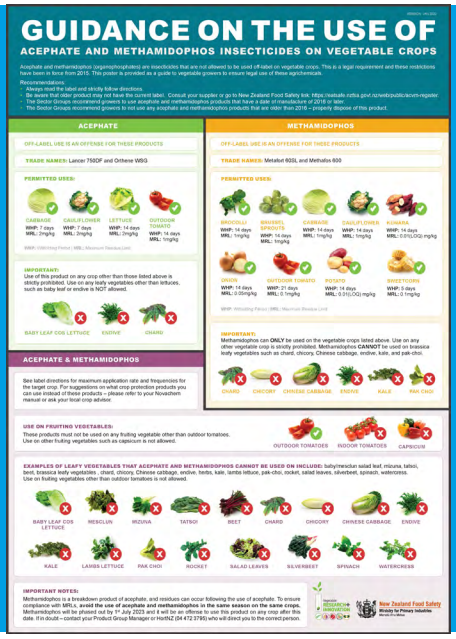
Deviations

Registrants wishing to deviate from this requirement to list a WHP by proposing a shorter or nil day WHP will be considered on a case by case basis. However, registrants must provide an argument on why a 1 day WHP is not applicable for that particular case. This argument should relate directly to the efficacy of the product. For instance, the fact that an active ingredient is exempt from MRL requirements would be insufficient to support a deviation from the requirement for a WHP.

The change took effect 21 January 2020. However, if a registrant is close to finalising and submitting an application that includes a nil day WHP, the ACVM team will still accept it at pre-screen but will assess it on the basis of a 1 day WHP. Alternatively, the registrant can contact us to discuss options on how to proceed with the application.

Label updates

Product labels with an existing nil day WHP will be updated when a variation application is made, or the registration is renewed, or no later than two years from 1 January 2020. (We appreciate that for a time there will be a mixture of nil and 1 day WHPs.)



A colourful new A3 poster on the use of acephate and methamidophos insecticides on vegetable crops is now available on our website.
Check it out: POSTER

The poster is a joint project between Vegetable Research + Innovation and New Zealand Food Safety.

FYI

Antibiotic review update

We have requested applications to progress the reassessment of currently registered veterinary medicines containing macrolide, later-generation cephalosporin, and penicillin active ingredients. (The summary report for the review of this first tranche of antibiotic reassessment work is on the website.)

The reassessment will re-evaluate all current veterinary medicine registrations containing antibiotic active ingredients in these classes to ensure that the controls applied to these products are fit for purpose, and that all risks associated with their use including the risk of antimicrobial resistance are appropriately managed. The reassessment will also:

- apply the antibiotic importance classifications established in the first tranche review to all products containing these antibiotic active ingredients
- review and revise maximum residue levels (MRLs) as required.

The deadline for application submissions is 31 March, with public notification of the reassessment to follow.

The review of the second tranche of antibiotic classes, which includes currently registered veterinary aminoglycosides, fluoroquinolones, lincosamides, and first and second generation cephalosporins, is currently underway. We anticipate that the second tranche review paper will be available for registrant review in late March/early April, with publication to the website after that.

Codex update

Assurance Director Allan Kinsella and Assessments Team Manager Jenni Doyle attended Codex Task Force Antimicrobial Resistance (TFAMR07) in Pyeong Chang, South Korea, in December 2019. The Task Force is working on a revision of the Code of Practice to contain and minimise foodborne AMR and is developing Guidelines on Integrated Monitoring and Surveillance of Foodborne AMR. At the meeting the Code of Practice document was discussed in detail, and it was agreed that the proposed draft would be recommended for adoption at step 5. An electronic working group, which will be chaired by USA and co-chaired by Chile, China, Kenya and UK, was established.

Due to the time taken on the Code of Practice, the draft Guideline on Integrated Monitoring and Surveillance of Foodborne AMR was not discussed. TFAMR07 agreed to return the proposed guideline to step 2/3 for redrafting and to establish an electronic working group chaired by the Netherlands and co-chaired by Chile, Canada, China and New Zealand. The last meeting for TFAMR will be held in South Korea in December 2020, when both documents are expected to be completed.

MRL promulgation process update

We have received lots of positive feedback from our article in the December 2019 *News and Views* about our trial of fixed cut-off dates for MRL promulgation.

We are pleased to tell you that we have the following MRL rounds underway:

- September 2019:
  Public consultation finished on 11 February 2020. Four submissions were received and we are currently working through these. We expect MRLs to be promulgated in early March.
- February 2020 (cut off 1 January):
  This included two exemptions from the requirement for an MRL for veterinary medicines, and public consultation is currently underway. This will finish on 3 April.
- Depending on the submissions we receive, we expect these to be promulgated in early May.

The cut off for the next MRL round will be 1 March, and public consultation will start in early April.
Subsequent MRL rounds this year will have fixed cut-off dates of:

- 1 June
- 1 September
- 1 December.

If you have any questions or feedback about the MRL process or timeline, please contact:
Awilda.Baoumgren@mpi.govt.nz

team update

David Tran (Adviser Regulatory Programmes)

"I joined the ACVM team in mid-November 2019, and I have been working on the Restricted Veterinary Medicines (RVMs) Operating Plans (OP) project among many other things! Prior to MPI I have worked in pharmaceuticals, research and commercial laboratories in New Zealand and overseas. Outside of work I enjoy hiking/tramping, pub quizzes, and going to the gym."

Teresa Robinson (Adviser Compliance)

"I've recently joined the ACVM Regulatory Programmes team. You may have seen me around before as I originally joined MPI in 2014 as an adviser in the Approvals Operations Team. I left to go travelling during 2016-17 and came back to my role in 2017 when I was briefly seconded into the Animal Welfare Sciences team. Over the last few years I have built up my knowledge of the ACVM Act and Regulations and look forward to working in the compliance space in the new Regulatory Programmes team.

I have a Bachelor of Applied Science in Animal Management and Welfare and a Bachelor of Science in Zoology and Marine Science. In my spare time I enjoy watching rugby, being active and travelling."

ACVM team restructure and resourcing

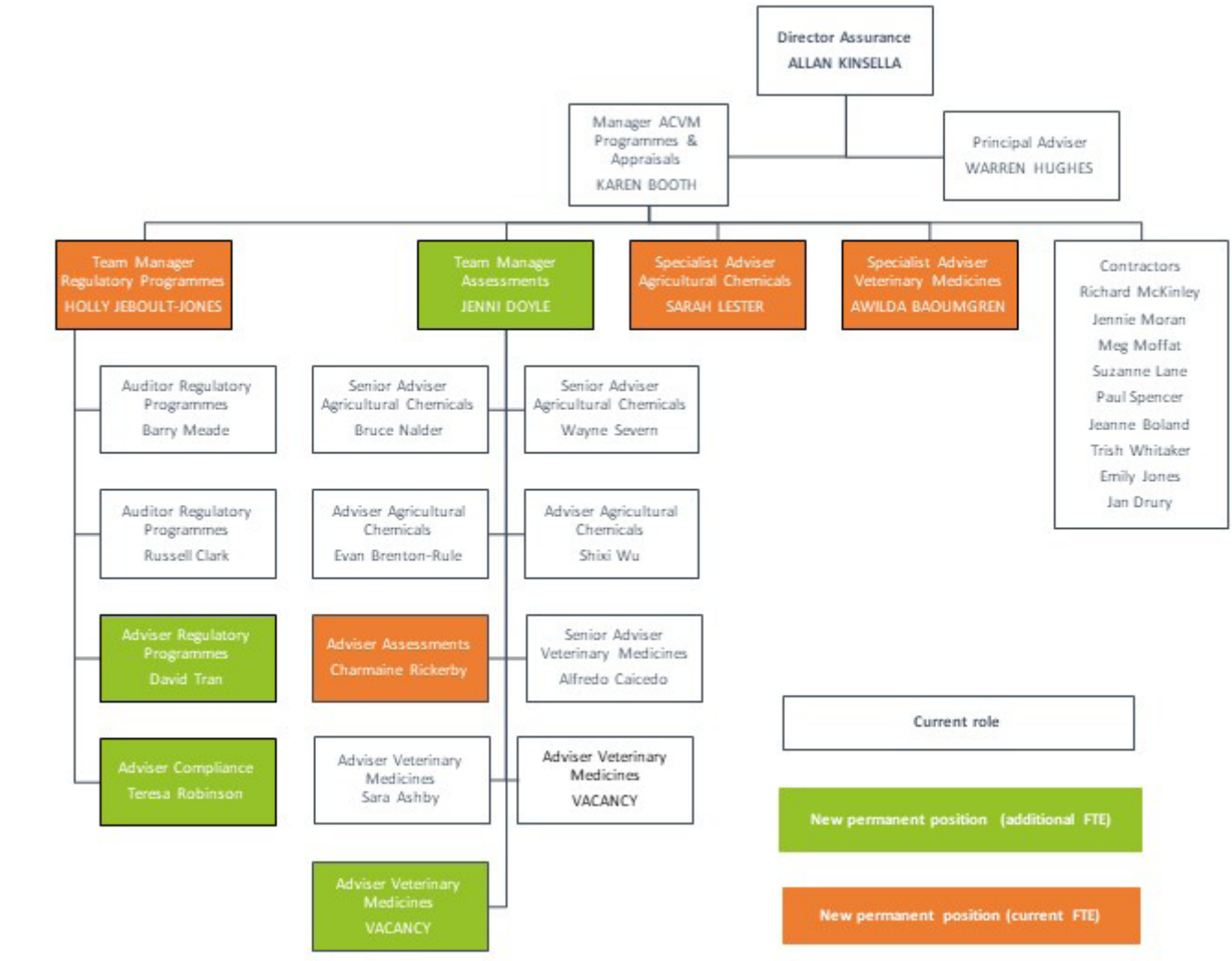
The ACVM team completed a restructure in September 2020. The key drivers and objectives for the restructure were to:

- clearly allocate resources for key functional areas (i.e. appraisal, Good Manufacturing Practice (GMP) and compliance)
- implement a structure best positioned to deliver operational excellence through achieving our core service accountabilities
- strengthen cross-pollination in technical areas (agricultural chemicals and veterinary medicines).

The new structure has resulted in the creation of two new teams and team managers (Assessments and Regulatory Programmes), and two specialist adviser roles.

Team Manager Regulatory Programmes is Holly Jeboult-Jones. Holly is responsible for the GMP audit function, regulatory programmes (including RVM Sellers Operating Plans, the adverse event reporting programme) and the compliance function.
Team Manager Assessments is Jenni Doyle. Jenni is responsible for the technical assessment team, and is the contact person now for enquiries relating to applications.
Specialist Adviser Veterinary Medicines is Awilda Baoumgren. Awilda is responsible for providing advice to the Manager ACVM Programmes & Appraisals on technical, policy and industry related issues, setting of MRLs under the Food Act and interfacing with other MPI teams and industry sectors in the regulatory oversight of veterinary medicines, including Food Safety and Trade.
Specialist Adviser Agricultural Chemicals is Sarah Lester. Sarah is responsible for providing advice to the Manager ACVM Programmes & Appraisals on technical, policy and industry related issues, setting of MRLs under the Food Act and interfacing with other MPI teams and industry sectors in the regulatory oversight of agricultural chemicals, including Food Safety and Trade.

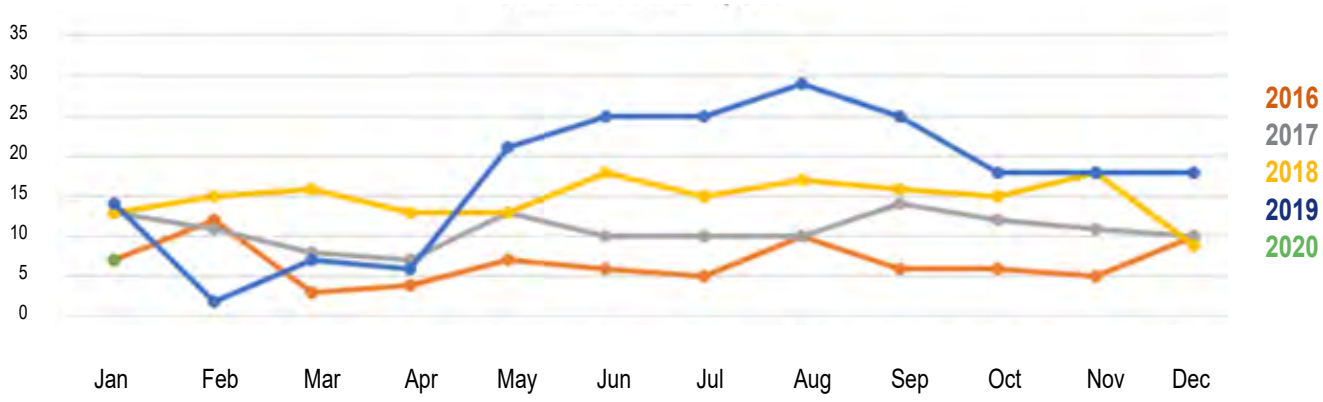
A new permanent position (Adviser Veterinary Medicines) has recently been created in the Assessments team, to assist with the backlog and application volumes in the veterinary medicine space. Consequently we are now recruiting for two Adviser Veterinary Medicine assessors.



Performance Metrics

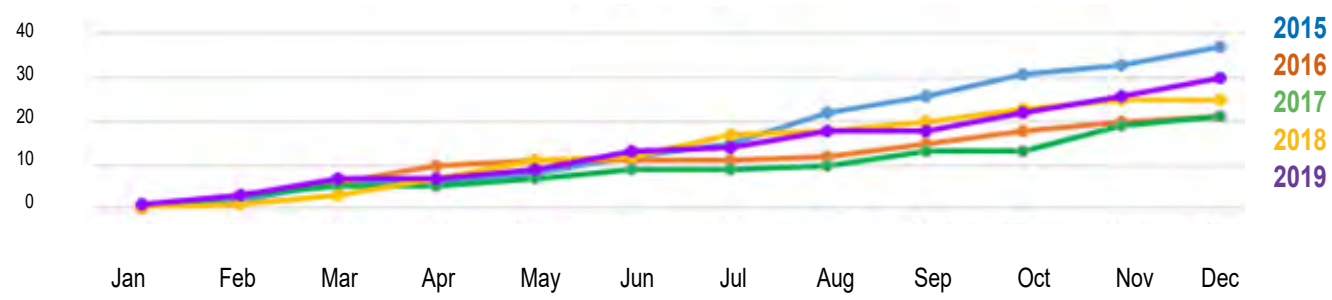
Over 200 compliance related activities were logged in 2019, an increase from previous years. This reflects the additional resource and focus in the ACVM team on compliance. The majority (76%) of non-compliance reported events in 2019 have been actioned and closed, 11% are pending internal action, 11% are pending external response, and three (2%) were referred to the MPI Compliance team.

Total Compliance Related Activities
including reported non-compliance events, batch specific variations, regulatory alerts and non-conformance reports



There has been an increase in the number of GMP audits performed in 2019, due to the two new auditors hired in 2019.

Cumulative Annual Good Manufacturing Practice (GMP) Site Audits Performed

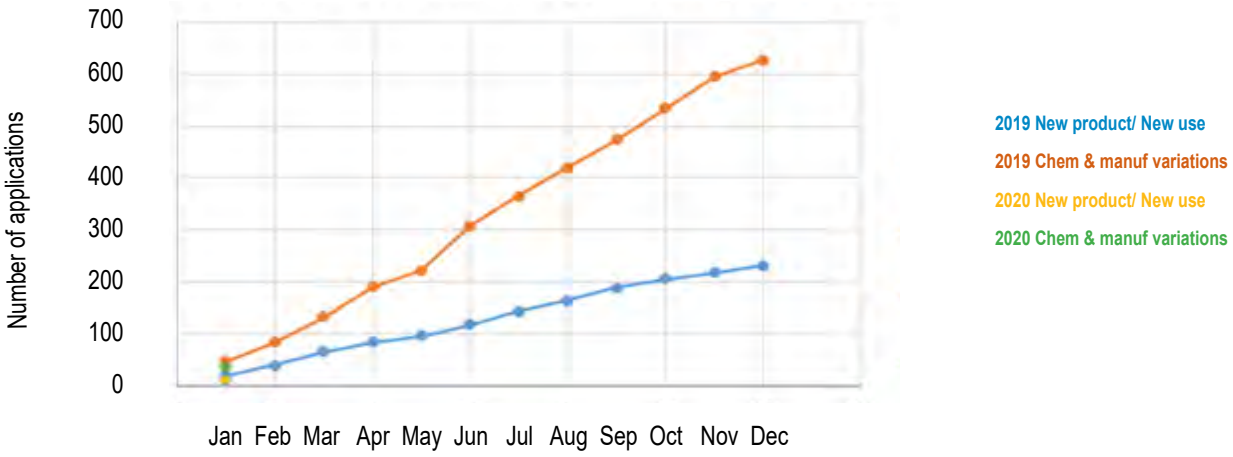


VACANCIES FOR VETERINARY ASSESSORS

We are looking for two veterinarians who are critical thinking risk managers to join the ACVM team as veterinary assessors. For job description and more information, contact ACVM manager Karen Booth (karen.booth@mpi.govt.nz)

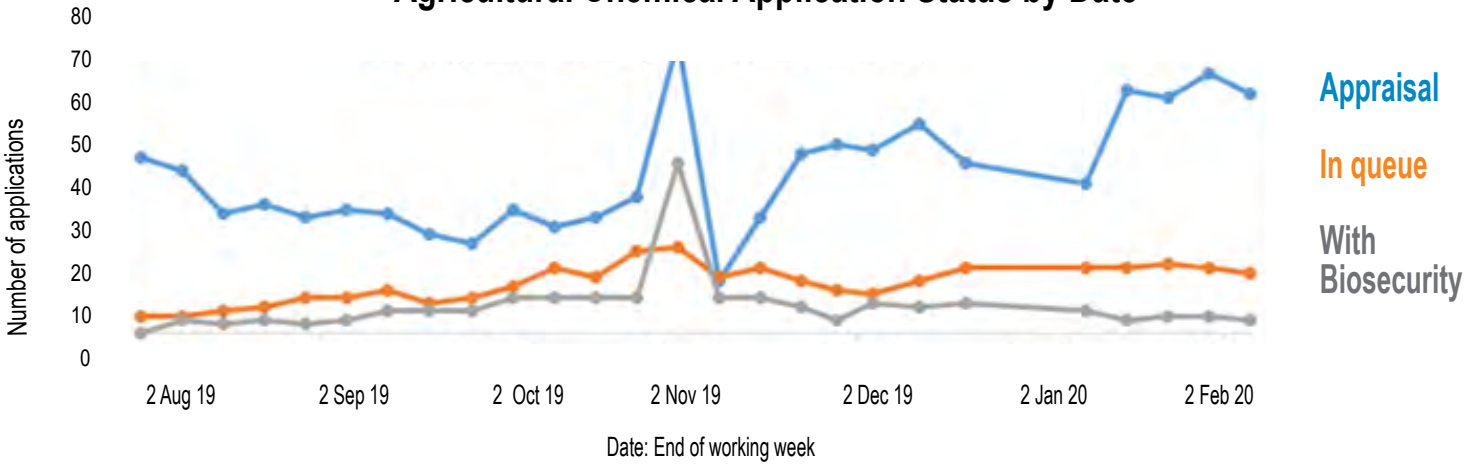
Approval volumes in January 2020 are similar to that in 2019.

2019 - 2020 ACVM Technical Application Approvals (Cumulative Volumes)



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

Agricultural Chemical Application Status by Date



There is still a significant backlog of Vet Med applications, which has been gradually increasing since the end of November. This is mainly due to being short-staffed in recent months (a vacancy in the vet med team since September 2019, and staff being on leave), and application volumes.

Veterinary Medicine Application Status by Date