Dec 2017

SAAM News & Views

ISSN 2230-4630

In this issue:

Holiday closure information

The MPI office will be closed from **23 December 2017 to 3 January 2018.** Many team members will take their annual leave following the Christmas closure, so there will be minimal staff 'on deck' when the office reopens.

For **EMERGENCIES** during the holiday season, contact:

Agricultural Compounds and Veterinary Medicines
Glen Bradbury (Manager), Mobile: 029 894 0253

Chemical and Microbiological Assurance
Mary Western (Manager), Mobile: 029 894 2547

Food Assurance
Sharon Wagener (Manager), Mobile: 029 894 2634

Website Subscriptions

If you haven't already subscribed to the MPI website, please do so. You will be notified when items of interest to you are published.

Reminders to ACVM Registrants

The period from 20 December to 15 January is off the clock as far as ACVM statutory timeframes are concerned.

From 1 January 2018, registration renewals will be for five years
(see September issue of *News & Views*, page 2).

Registrants of antibiotics, don't forget to send in your 2017 sales data to ACVM.Tech.Assessment@mpi.govt.nz

Ministry for Primary Industries
Manatū Ahu Matua

Products must comply with conditions

MPI wishes to remind all registrants, manufacturers, importers and sellers of agricultural compounds that these products must, at all times, comply with all relevant conditions in the ACVM Act and Regulations.

All companies that import, manufacture, or sell agricultural compounds must:

- know what the requirements for their products are (see below)
- have adequate quality checks and systems in place to ensure that the products sold in New Zealand meet ACVM requirements (this applies to products manufactured in New Zealand or internationally).

Products registered under the ACVM Act

The trade name product must comply with all the conditions of registration that form part of the product's registration. These include, for example, requirements and controls on ingredients, manufacturers, manufacturing process, labelling, packaging and restrictions on sale or use.

The conditions of registration for any trade name product can be found under that product's listing on the ACVM Register – Veterinary Medicines, Agricultural Chemicals, and Vertebrate Toxic Agents.

For registrants, the list of conditions of registration for your product can be found attached to the product's Certificate of Registration.

Products exempt from registration

The exempt product must comply with all the relevant conditions in the ACVM (Exemptions and Prohibited Substances) Regulations 2011, schedule 2 and regulations 7 - 15. These include being fit for purpose, manufactured according to a documented system, and provided with sufficient consumer information. For more information, please refer to the ACVM Notice: Agricultural Compounds Exempt from Registration.

Non-compliance

MPI regards non-compliance with conditions of registration, and conditions for exempted products as serious events, with resultant action likely. Further information regarding agricultural compounds can be found on the MPI website (see article on next page).

ACVM Annual Workshop

The ACVM annual workshop for registrants, New Zealand agents, consultants and data assessors will be on 23 February 2018. The workshop will follow the 22 February Agcarm Summer Conference. Both will be held at the Jet Park Airport Hotel & Conference Centre. At this stage topics to be covered include:

- ACVM update 2018
- Approvals Operations update
- Antimicrobial resistance
- Changes to the ACVM Regulations
- Registration Review Project update
- Break-out sessions for agricultural chemical registrants/interested parties, and veterinary medicines registrants/interested parties.

You are invited to submit any topics of interest you wish covered to approvals@mpi.govt.nz by 9 February 2018.

To register, go to https://www.eventbrite.co.nz/e/acvm-workshop-tickets-40306362415 to https://www.eventbrite.co.nz/e/acvm-workshop-tickets-40306362415

Registrations close on Friday, 9 February 2018, 4:00pm. Please register as soon as possible to assist with planning. **No-one will be admitted on the day of the workshop without prior registration.** Refunds will be provided up until the registration closure date above. We look forward to seeing you there!

Navigating the new website

ACVM web pages have been moved to the MPI website, which is considerably different from the Food Safety site. If you are having trouble finding ACVM information, this guideline is for you.

Finding ACVM
Go to the MPI home page (www.mpi.govt.nz) and click on Processing (the reason it is under Processing is a long story…) Under Processing, you will find "Agricultural compounds and veterinary medicines" plus the linked subcategories in the table below. You will also see photos that are not just to brighten up the page—they provide direct links to the ACVM product register, consultants, and importing.

We are working with the web team to make it easier to find information. Further developments will be in the next *SAAM News and Views.* **Please contact us if you have any specific issues or questions (approvals@mpi.govt.nz).**

Page	Content
Introduction to ACVMs	Information on ACVM products, New Zealand regulation of ACVMs, and a step-by-step explanation of the registration process
What is an agricultural compound?	Information on how you determine if a product is/is not considered an ACVM (class determination)
Veterinary medicines Agricultural chemicals Vertebrate toxic agents (VTAs)	Each of these categories includes a definition and information on authorisation, manufacturing, selling, and using, plus a link to relevant documents, e.g. labelling guidelines and application forms
Fertilisers	Definition and explanation of how product claims that go beyond the scope of the definition make the product an agricultural chemical that will likely require registration instead of a fertiliser. Also has information on requirements, importing, and exporting
Maximum residue levels for agricultural compounds	Requirements, links to the current MRL Notice, Codex MRLs, International MRL database, and how to request establishment of an MRL
Pet food and animal feeds	Links to requirements under ACVM and other legislation
Antimicrobial resistance	Current activities, sales reports, scientific papers and background material
ACVM exporting	Links to the MPI Exporting section covering steps to exporting, requirements, and forms
ACVM registers and lists	Links to ACVM product register, consultants, listed data assessors, manufacturers of veterinary medicines and VTAs, sellers of restricted veterinary medicines, GRAS list
ACVM alerts	This is a new category for domestic product alerts, e.g. the 2017 ergot poisoning in Southland, or international alerts that have been reported to MPI
ACVM newsletters	This is where *News and Views* lives—the issues are arranged by year
ACVM data assessors	Details on becoming a listed data assessor, any relevant communications from us (e.g. workshop information), plus all the templates for doing assessments
ACVM forums	Information on national and international groups relevant to ACVM activities

Welcome Back to Teresa Robinson!

We are very pleased to announce that Teresa, Approvals Operations Adviser, has rejoined the team. We are happy she had a great OE, and we are even happier that she is back.

International Events

Global Minor Use Summit 3 (GMUS3) and visit to the Veterinary Drugs Directorate, Canada 1-4 October 2017

Warren Hughes attended the above Summit, which was held in Montreal, Canada. Around 230 participants from 35 countries were in attendance, including two attendees from the New Zealand industry. Perspectives were given from all regions by regulators, producer sectors, and pesticide manufacturers.

Initiatives
A substantive list of initiatives was developed to facilitate minor uses and crops. These initiatives were grouped by activity areas, e.g. assessment, policy, and maximum residue levels (MRLs). New Zealand has already implemented a number of these initiatives, such as increased data protection, basing residue trial guidance on Organization for Economic Co-operation and Development (OECD) guidelines, exempting biopesticides from MRL requirements, and allowing imported food to comply with Codex MRLs.

Some initiatives that MPI could explore further, which should reduce cost to industry, are:
- inter-crop group extrapolations on residues
- accepting efficacy data from countries with similar geographic conditions, and
- greater sharing of data and/or regulatory assessment reports between regulators.

Veterinary Drugs Directorate
Attendance at the GMUS3 provided an opportunity for Warren to visit our equivalent veterinary medicine regulator, the Veterinary Drugs Directorate (VDD) in Ottawa. He presented an outline of the New Zealand regulatory system to VDD staff. Topics discussed included antimicrobial resistance, joint reviews, good manufacturing practice and VICH activities.

VICH Steering Committee and VICH Outreach Forum 12-16 November 2017

Glen Bradbury and Warren Hughes attended the Veterinary International Conference on Harmonization (VICH) meetings in Tokyo, Japan.

New Zealand's proposal to move from a 9 monthly to a 12 monthly meeting cycle was generally supported, subject to further work on meeting efficiencies.

A number of new and revised guidelines are progressing through the system. Guidelines of interest are:
- extraneous virus testing of biologicals
- anthelmintics
- combination products, and
- bioequivalence.

At the VICH Outreach Forum, two new country attendees (Nigeria and Zimbabwe) presented their national registration systems. Other presentations covered harmonisation and collaboration in South American and Asian regions along with a discussion on implementation of pharmacovigilance systems.

Data Assessment: Registrant's Responsibilities

- It is your responsibility to ensure the entire package, including relevant data assessment reports, is complete and robust.
- You should carefully review all Data Assessment Reports that you receive.
- The data assessor will identify any deficiencies and non-conformances. You should ensure that you have addressed all of these before submitting the application to MPI.
- Please remember that data assessors can't make arguments for you. This is your responsibility.
- You may provide feedback on Data Assessment Reports to the data assessor.

FYI

E-Files for ACVM applications

The public consultation period closed 24 November 2017, and no submissions were received. The revised guideline has been published on the MPI website, and takes effect from the date of publication. We recommend all applicants make themselves familiar with the guideline before submitting their application documents and supporting information.

The guideline specifies the basic parameters required for an acceptable electronic submission. A well-constructed, named and indexed submission expedites the screening and review process, and reduces assessment time and associated fees. Note that application files that do not comply with this guidance may be rejected at screening.

MRL consultation

Food Act Notice: Maximum Residue Levels for Agricultural Compounds
This round of proposed changes to the Notice includes:

- a new definition for 'active ingredient'
- new and amended MRL entries for eight agricultural chemical and veterinary medicine active ingredients
- three proposals for new or amended exceptions from compliance with an MRL.

The consultation document is available at this link.
Send your submissions to: ACVM.Consultation@mpi.govt.nz

Consultation closes at 5pm on 29 Jan 2018.

ACVM working digitally

As of 1 November 2017, all applications are now processed electronically, including the issuing of approval documentation. Registrants were advised via email in October, and the majority have indicated their preference for receiving approval documents in digital format. This is a significant change in the registration process. Initial indications are there will be internal efficiency gains and registrants will receive approval documentation sooner (compared with post).

Updates from the Chemical and Microbiological Assurance Team

New reports on the website

MPI regularly monitors food produced, sold in, and exported from New Zealand for a very wide range of contaminants and chemical residues that could pose food safety and/or market access risks. The residue monitoring programmes are part of MPI's food safety verification system, which provides end point confirmation that MPI's regulations and industry practise are working together to manage risks to consumers.

Regular and ongoing publication of reports from MPI's main food residue monitoring programmes reinforces the strength and suitability of New Zealand's food safety system and fulfils the information needs of many different stakeholders. The Chemical and Microbiological Assurance team has recently published six reports to the MPI public website:

- National Chemical Contaminants Programme
  Processed Fresh Milk Survey 2015
  National Chemical Contaminants Programme
  Raw Milk Result Summary (July 2016 to June 2017)
  National Chemical Contaminants Programme
  Dairy Milk Powder: Radionuclide Results (2013/14, 2014/15 & 2015/16)
- National Chemical Contaminants Programme
  Dairy Products and Raw Milk: Dioxin, Dioxin-like PCB, and Indicator PCB Results (2014, 2015, and 2016)
- National Chemical Residues Programme
  Results for 1 July 2016 - 30 June 2017
- Food Residues Survey Programme (FRSP)
  Survey of agricultural compound residues in commercial foods for infants and young children (2016)

National Microbiological Database

A proposal to amend the Animal Products Notice: Specifications for National Microbiological Database Programme was published on 5 December 2017 with a closing date for submissions of 12 January 2018. The proposed changes are intended to clarify some of the procedures and to make some minor corrections to the text.

E-STAR transition

MPI has developed a new Electronic Sample and Testing Attribute Repository Database (E-STAR) to support monitoring programmes run by the Chemical and Microbiological Assurance (CMA) team and to replace two legacy databases currently in use. The National Microbiological Database (NMD) Programme transitioned to E-STAR on 2 October 2017, and further development work is continuing to enable transition of the remaining monitoring programmes in the New Year.

CMA staff changes

Nicola Sparrow
Nicola has been with the CMA team for over 3 years as an Adviser, primarily in the National Microbiological Database (NMD) area. A recent vacancy provided her with a well-earned opportunity to become a Senior Adviser. She will continue to work on NMD and is now directing the transition from our legacy databases to E-STAR (see article above).

Shelly Gardner
Shelly has joined the CMA team, bringing 6 years' very relevant experience at an analytical laboratory. She'll be working alongside the Principal Adviser Residues implementing the Dairy National Chemical Contaminants Programme.

Sarah Howison
Sarah has joined the CMA team bringing valuable recent experience from the dairy industry. She'll work across a number of programmes, including the Food Residue Survey Programme and imported food monitoring.

Registration of Food Importers

The Food Act 2014 requires all imported food for sale to be imported via a registered importer.

There was a transition period provided in the Food Act 2014, but this period ended 1 July 2017 and all importers of food for sale should now be registered. Note that dietary supplements, wines, beer and spirit are all considered to be food under the Food Act and therefore this requirement applies to businesses importing these products.

Under the previous legislation, food importers were listed with MPI. Registration under the new Food Act is different from this earlier listing.

How to register
Information on how to register is on the MPI website at www.mpi.govt.nz/importing/overview/food-imports/ or for further help contact approvals@mpi.govt.nz. Phone 0800 008 333 or 04 894 2550.

Registered Food Importer details are shown on the public register at http://mpiportal.force.com/publicregister/FoodImporter. If you are a food importer, it is important that you check this register to ensure you are on it.

Failure to register
Importing food for sale without being registered with MPI is an offence under section 234 of the Food Act 2014. In addition, section 109 of the Food Act 2014 requires importers to be registered before food clearance is given to consignments of high risk food (i.e. High or Increased Regulatory Interest Food.)

Food Assurance in conjunction with Verification Services and Approvals is now pro-actively identifying importers of food that are not registered.

Ensuring awareness
Initially, MPI is communicating directly with these importers to ensure they are aware of their obligations and given time to comply. If importers fail to comply, enforcement activities may be taken. For example, an infringement notice with a fee of $450 may be issued.

MPI is initially focusing their efforts on importers of higher risk products requiring clearance at the border and on large importers.

General communications have also been sent out via Customs Brokers to ensure they are aware of the obligation and requesting that they encourage their clients to register.

Multiple Release Permits / New Zealand Importer Assurance Scheme

The Food Assurance team is currently reviewing the New Zealand Importer Assurance (NZIA) Scheme. Under this scheme food importers are issued a certificate (the NZIA) based on an acceptable audit of their import business. Holders of NZIAs are able to clear high risk food products without the need for MPI Food Safety Officers to inspect, check for certification require sampling and testing of the product. Prior to the Food Act 2014, this clearance option was facilitated by the issue of Multiple Release Permits (MRPs). Twenty-two importers have recently been transitioned from MRPs to NZIAs.

Importer interviews
Food Assurance team members Ann Oliver and Lorna Zach teamed up with David Ball (Senior Service Designer) to visit and interview importers who are currently in the scheme and their brokers. These interviews were designed to gain a better understanding of the importers' businesses and to determine what they think of the current scheme -- both good and bad. The findings from the interviews are currently being analysed and insights and opportunities from these discussed. We will share the findings as soon as possible. Look for an update in the next *SAAM News and Views*.

Farewell to Tasha Williams

Tasha has been the Specialist Adviser Food Assurance for five years. She departed the Food Assurance team early this month to take up a role as Specialist Adviser Market Access – South-East Asia based in Wellington at Pastoral House.

We thank Tasha for her outstanding contributions to the team and wish her all the best.

Manuka honey export requirements

MPI's work to establish a regulatory science definition for New Zealand mānuka honey exports is progressing well.

The Food Assurance team and other relevant teams in MPI facilitated formal consultation on the proposed definition and other measures for strengthening our export regulatory framework between 11 April 2017 and 13 June 2017. This also included a series of public meetings in Alexandra, Christchurch, Gisborne, Hamilton, Nelson, Palmerston North, Wellington and Whangarei, which were well attended.

MPI received 120 submissions during the formal consultation process. Those submissions have been analysed and MPI is in the process of finalising our formal response to the submissions.

staff---staff---staff---staff---staff---staff---staff

Ann Oliver

The Food Assurance team has been allocated an extra full-time position. This position, 'Senior Adviser Import and Export Assurances', was recently advertised and we are pleased to say that Ann Oliver will move into this role. Ann currently works across two areas:

- food imports, and
- monitoring and evaluation under the Food Act Implementation Programme (FIP).

The change will mean Ann moves out of monitoring and evaluation for FIP but picks up more in the exported food space.

Stacey Ramchand

Food Assurance will welcome Stacey Ramchand as Senior Adviser Food Assurance. Many of you know Stacey as she has been working at MPI as the Senior Adviser Verification in the Food and Beverage team.

"He sees you when you're sleeping. He knows when you're awake."

Maybe accepting that 'friend request' was a mistake....

Happy Holidays from SAAM.

We wish you all a safe, healthy, and relaxing holiday season!