ACVM

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Manatū Ahu Matua

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Changes to MPI structure affect ACVM Group

Part of the organisational structure of MPI was changed last month, and the ACVM Group has been split into two key areas. The technical assessment functions have been moved to the newly established Systems Audit, Assurance and Monitoring Directorate under Director Allan Kinsella*. This move places the standards setting, appraisal and audit functions into a specialised area and is intended to improve information transfer, technical expertise and resource in the five key risk areas (welfare, residues, efficacy, trade and domestic food standards).

The SAAM Directorate will provide assurance that New Zealand's food safety systems, primary industry programmes and manufacturing premises are being operated in line with MPI's regulatory and non-regulatory standards and MRA agreements, through fit for purpose chemical/microbiological monitoring, product registration, assurance, certification, systems audit and pharmacovigilance programmes. It will also regulate and develop standards relating to agricultural chemicals, veterinary medicines, vertebrate toxic agents and maximum residue limits (MRLs) to ensure risks to animal welfare, trade, biosecurity and human health through the import, manufacture, sale and use of these products are adequately managed.

The Approvals Operations Team and Manager are now part of the Branch Planning, Systems and Support Directorate, with Debbie Morris as Director. However, the process in managing ACVM applications will not change. The Operations Team will still be the entry point for all ACVM applications via the approvals@mpi.govt.nz email and/or via post. The team will process and manage applications and will be the first point of contact for any queries and concerns on ACVM matters. The Operations Team will work alongside the Technical Team to ensure a seamless process.

* Allan Kinsella, who has a Bachelor of Arts and Masters of Business Administration, joined the Ministry of Fisheries after 20 years in the New Zealand Defence Force (NZDF). He ended his NZDF career working in the corporate environment in management roles focussed on improvement of corporate services, performance management and capability development. Allan

served on operational tours in East Timor as a Deputy Battalion Commander and as the Senior Operations Officer for the United Nation's Mission in Sierra Leone.

Allan's first public service role was managing Ministry of Fisheries strategic projects, including the Observer Services Strategy Review, which involved collaboration with industry groups, ENGOs and other government agencies. The review aimed to improve the efficiency of current service delivery and develop operating standards.

Since the merger of the Ministry of Fisheries and Ministry of Agriculture and Forestry, Allan has worked in the Office of the Director-General as the Manager Strategic Portfolio and is currently the Manager Strategy and Planning.

Data assessor recognition

Last month people who had indicated an interest in being part of the Recognised Data Assessor Process Working Group were contacted about preliminary workshops to consider the recognition process. Workshops were held in Wellington and Auckland.

Please note that these workshops are about the process and that workshops to become a recognised data assessor will follow once the process is confirmed.

Two draft documents, the Recognition of Data Assessors Information Requirements and the ACVM data assessor application form, are available for anyone who would like to participate in the development process through email feedback.

Contact Sarah Lester (sarah.lester@mpi.govt.nz) for copies of the documents or to be put on the list for the "Becoming an ACVM Recognised Data Assessor" workshops.

Food Act 2014 and MRLs

The Food Bill has gone through all the required processes and is now the Food Act 2014. When the Food Act 2014 comes fully into force (March 2016), it will replace the Food Act 1981.

The Food Act 2014, like its predecessor, provides for the establishment of maximum residue limits (MRLs) for agricultural compounds. However, the process will change. MRLs under the new regime will be established by a notice approved by the chief executive of MPI. The criteria that the chief executive will need to consider before establishing an MRL will be provided in Regulations. MPI will consult on the development of those Regulations.

Consultation on proposed MRLs will be a part of the process, as it is currently. The changes in process should shorten the timeframe for establishing MRLs, which will be good news for industry.

Until the Food Act 2014 takes full effect in March 2016, the existing process remains in place.

Adverse event reporting update

It has been a busy six months for adverse event (AE) reporting with 529 reports received compared with 178 reported over the same time last year. The Compliance Team within the ACVM Group considers the increase in cases reported indicates an improved awareness of this programme within industry rather than specific product quality issues.

The engagement of registrants involved in recent product recalls and more serious adverse events reported to MPI has been outstanding. This gives us confidence that, in most situations, the required product responsibility in the marketplace is in place.

The AE reports received are still predominantly relating to veterinary medicines that have been used off-label. So far this year, we have received only one AE report that involved an agricultural chemical and none involving vertebrate toxic agents. With such low reporting numbers for these product types, it is difficult to establish if inappropriate under-reporting is occurring within these groups. MPI's current expectation is that ALL unfavourable or unintended events that are potentially related to product use, and that may or may not be identified on the product label, are classified as adverse events and should be reported. This also includes any product quality issues such as packaging failure, product sedimentation and application difficulties.

We thank those who have given us feedback during the review of the AE reporting procedures. Your input has been valuable and has helped shape the final format of the first annual AE summary report, which is on track to be published on our website in December.

Approval of veterinary medicine manufacturing changes

The ACVM Group is reviewing how we approve vet med manufacturing-related changes and, as a result of this process, we have started requesting supporting information when manufacturers and manufacturing processes are approved or amended.

GMP approved manufacturing facilities are required to conduct process validation to ensure that a manufacturing process, operating within established parameters, can perform effectively and reproducibly. We also expect that any changes to premises, equipment or processes that may directly or indirectly affect the quality of a product are qualified and validated.

Validation verification helps support additional information provided during product assessment to verify that a product can consistently meet its release and expiry specifications, and an established level of quality for the product's intended purpose. We are requiring verification of process validation when there is an application submitted to vary the manufacturing process, equipment or materials, or to add or amend a manufacturing site.

These information requirements are being made to align more closely with GMP requirements and international standards to ensure that all risks are being adequately managed, and to confirm that the product is still capable of consistently meeting the pre-determined conditions. If process validation reports cannot be provided, adequate justification verifying why any change does not impact product quality, stability or previously assessed data will be required. If justification is not sufficient, full data packages including stability data may also be necessary.

This change, along with clarification on a number of chemistry and manufacturing related issues, will be included in the revision of the Veterinary Medicine Chemistry and Manufacturing Information Requirements, which will be completed later this year.

Documents and forms update

What's on a label?

ACVM requirements for labelling veterinary medicines, agricultural chemicals and vertebrate toxic agents have been updated. We thank industry members who commented on the drafts. All suggestions were considered, and those that had merit but will have consequences in other areas have been 'captured' for the next review.

Labelling Veterinary Medicines

Labelling Agricultural Chemicals

Labelling Vertebrate Toxic Agents

Provisional registration and research approval

Revised provisional registration and research approval application/product data sheet (PDS) forms are now available on the website and should be used from now on. Changes to the forms have been mainly to clarify requirements, to align them with the other PDS forms, and to include industry suggestions to make them more 'user-friendly' (for example, these forms are no longer protected).

Registration and Product Data Sheet for Provisional Registration (or Variation of Existing Provisional Registration) of Agricultural Chemical or Veterinary Medicine or Vertebrate Toxic Agent

Product Data Sheet for Research Approval (or Variation of Existing Research Approval) of Agricultural Chemical or Veterinary Medicine or Vertebrate Toxic Agent

Registration application form

In February, we introduced a new application form for registrations, registration renewals and variations. Our intent was to replace the formal letter previously included with applications, but that goal has not been achieved.

From industry, we have received mixed reviews—some people have said how much they like the new form and some have sent us reports that the form will not print, causes computers to freeze, and so on. From our perspective, we are getting applications without most of the required information—in a few cases it is even impossible to tell what the applicant is requesting.

Therefore, we are re-thinking the form to reduce the graphic elements, make the requirements more obvious and, hopefully, achieve our original intent. Watch this space!

Staff update

We are pleased to welcome two new Advisers in the Operations team: **Andrew Barrowclough** and **Teresa Robinson.** By way of introduction…

"Hi, I'm Andrew. I grew up in Auckland although I was born in London. After secondary school, I moved to Dunedin to study Politics and Anthropology. After finishing university I worked for a not-for-profit community service organisation.

I enjoy playing and watching all sports, especially football. I also love to travel, and was lucky enough to spend 2013 travelling and volunteering throughout Europe, visiting Portugal, Germany and Poland. I have also spent time in South-East Asia in Thailand, Vietnam and Cambodia."

Teresa says:

"I recently graduated from Unitec in Auckland with a Bachelor of Applied science – Animal Management and Welfare. Prior to that I went to Otago University and graduated with a Bachelor of Science - Zoology and Marine Science.

During my time in Auckland I volunteered and worked part-time for Mobility Assistance Dogs. Mobility Dogs train dogs to assist people living with long-term physical disabilities. I thoroughly enjoyed working with them and appreciate the great work they do."

Another new arrival

Not a new staff member, but a very welcome new arrival is Reuben William, born to Natalie and Matt Sanders on 2 May. Natalie, one of our Operations Advisers, is on parental leave until April 2015.

Codex Committee on Pesticide Residues (CCPR)

5-10 May, Nanjing, China

Warren Hughes and Dave Lunn from MPI along with Nikki Johnston from Market Access Solutionz attended the 46th CCPR meeting.

Items of interest include:

- Almost all (343) of the 360 or so draft MRLs proposed by the 2013 Joint FAO/WHO Meeting on Pesticides Residues (JMPR) were progressed to Step 5/8 (for adoption as Codex MRLs at the 2014 Commission Meeting), with virtually no opposition.
- The Committee finalised the revision of its Risk Analysis Principles after four years of discussion.
- Progress was made in updating the Codex Classification System for Crops/Feeds, although in the fruiting vegetable revision there is some disagreement on how to split edible and inedible commodities.
- The Minor Use Electronic Working Group (MUEWG) reported back to the Committee. One of its proposals was to move kiwifruit from a minor crop to a major crop. New Zealand indicated its concern and the matter will be re-considered by the MUEWG.
- The Committee agreed to revoke Codex MRLs for lindane as no country has any products approved containing it (this is based on the Stockholm Convention where Lindane is listed in Annex A). The Codex MRLs will be replaced with EMRLs and countries will be requested to supply monitoring data to JMPR later this year.

For more information contact Warren Hughes (warren.hughes@mpi.govt.nz)

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