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dedicated staff. This project comprises an end-to-end review of the entire registration process.

Objective

The objective of the review is to streamline internal processes, enabling consistent and timely processing of applications. This work will support our business objectives of meeting both statutory timeframes and key performance indicators as agreed with industry. Process mapping has been completed and the team has commenced the first round of internal workshops.

In conjunction with the review, we are continuing to look at assessment activity that can be carried out by the Operations Team to reduce multiple handling and allow the Technical Team to focus on more complex assessments and ensuring the overall robustness of the process. We are also exploring various pathways, as utilised by other international regulatory agencies, that we could use to manage minor variation applications.

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Registration Review

We have established an ACVM registration review project team* of three

Decision process

Our current focus is on the delegate decision process. We are looking at options for enhancing the integrity of the process while removing unnecessary process steps. Initiatives being considered include:

- re-establishment of the Technical Consultative Committee (under another name)
- presentation of information to facilitate quick, paperless processing
- clarification of the appeals process.

Request for more information

The formalised process for requesting additional information under section 11 of the Act has been trialled with several

registrants. This has had internal benefits, but we will seek industry views before finalising the system.



* The project is being led by Karen Booth. Karen is a veterinarian with 18 years' experience in regulatory affairs, most recently as the Regulatory Affairs Manager

at Zoetis. She brings both her experience and industry perspective to the project team.

ACVM Workshop

Sudima Hotel, Auckland Airport
25 February 2016
(following Agcarm Conference)

If you have suggestions for topics,
contact Maree Zinzley
maree.zinzley@mpi.govt.nz

Detailed information will be available in January.



Swede Associated Toxicity in Dairy Cattle

MPI has been working with industry since November 2014 to identify the cause of a higher than expected level of deaths of Southland cattle after they were fed swedes (of herbicide tolerant and non-herbicide tolerant varieties).

Industry investigations, primarily by DairyNZ, are now complete. A final report on the situation is under review by MPI and an independent veterinary pathologist. When this review is completed in late 2015, the report will be made available.

The investigation has identified that the deaths were linked to high concentrations of glucosinolates, which are naturally occurring compounds that can be toxic to cattle at high concentrations. The increase in deaths was due to multiple factors including changes in feeding practices, changes to climatic conditions that affected crop growth, and exposure of high risk animals (cows at calving) to higher concentrations of glucosinolates.

A working group will be set up to work through the report findings and establish an ongoing management strategy. Examples of future actions include providing advice to farmers to help them manage the risks associated with feeding swedes, and gaining accreditation for a method for detecting glucosinolates.

Neonicotinoids and Bee Health

MPI and the Environmental Protection Authority (EPA) are maintaining a watching brief of international developments on neonicotinoids and their potential impacts on bees. This includes monitoring the European two-year restriction on the three neonicotinoids, and whether this has any effect on bee health in Europe.

All data relating to restriction was due to be submitted to the European Food Safety Authority (EFSA) for its consideration by September 2015. MPI and EPA are waiting for their conclusions and recommendations in order to determine what, if any, actions need to be taken in the New Zealand context.

In recent years New Zealand's beehive numbers have increased to an all-time high of 575,000 colonies, and honey production is also at record levels. Despite this increase in bee colony numbers, MPI has co-funded a bee health survey together with the bee industry to better understand causes of bee colony losses in New Zealand.* Results of this survey, which is currently underway, should be available in 2016.

Given the importance of pollination to New Zealand's primary industry sector, MPI takes the issue of bee health very seriously. If new information indicates neonicotinoids are causing significant bee safety issues, then MPI will have discussions with EPA on whether these products should be reassessed under the Hazardous Substances and New Organisms Act 1996.

* Hive losses that have been investigated by MPI to date have been linked to high levels of the varroa mite.

Data Assessor Workshops

In November, we held workshops for listed veterinary medicine and agricultural chemical data assessors on residue data assessments. The workshops were attended by external data assessors and MPI staff from ACVM, Chemical and Microbial Assurance, and Plant Exports. Our thanks to all participants.

As well as providing general background information about international requirements, MRL setting, monitoring and compliance, the workshop topics covered:

- technical assessment of residue data
- writing a residues data assessment report
- data analysis
- statistics and animal transfer.

For information about [data assessor listing](#), check out our website.

NOTICE TO REGISTRANTS:

Some annual fees are still unpaid. Products with unpaid annual fees will now go through the de-registration process unless you have made contact with MPI Finance or the Approvals team.

Biosecurity clearance

We have met with heads of Agcarm to discuss issues with the biosecurity clearance process and the need for a clearance not older than three years. (See [September 2015 ACVM News and Views](#) for background.)

The requirement for renewal of the clearance authorisation is due to changes in MPI's Animal Imports Team, and we are arranging for an Animal Imports representative to cover this topic in the ACVM workshops to be held in February. (Workshop notice on page 1 of this issue.)

Feeding medicated calf milk replacer to bobby calves

We will be presenting, via AVMAC, a discussion document regarding medicated calf milk replacers and their associated withholding periods. The paper seeks information from regulated parties and stakeholders on current feeding practices for the purposes of determining whether additional guidance is required or whether withholding periods need to be reviewed.

Fertilisers discussion paper

Submissions on [proposed changes to regulatory oversight of fertilisers](#) under the ACVM Act and its regulations close 18 December 2015. We will provide further information in the next issue of *News and Views* following analysis of submissions received.

Operating plans for RVM sellers

Consultation on *Approval of Operating Plans for Sellers of Restricted Veterinary Medicines* is underway. Relevant industry groups and holders of currently approved operating plans have been asked to comment by mid-January 2016.

What's coming in 2016...

Reassessments

The following reassessments have been proposed:

- Amitraz
- Bismuth

The registrants of affected products have been contacted for comment and a decision to proceed will be made by the end of the year.

The following reassessments/reviews are being considered for next year:

- Anticoagulants
- Calcium injectable products
- Carbadox
- Clenbuterol
- Dichlorvos
- Dimetridazole
- Key Strepto*
- Nonylphenol ethoxylates

* Review of conditions only

Systems Audits

The following audits are proposed for next year:

- Manufacturing of Agricultural Chemicals (information gathering to inform regulatory controls)
- Research, Training and Testing Organisation Operating Plans (fitness for purpose)
- Agricultural Chemical Shelf Life Management (compliance)
- Sale and Use of Restricted Veterinary Medicines (compliance with conditions and authorisations)
- Manufacture and Sale of Fertilisers (compliance with exemption regulations and information gathering)
- Waste Stream Feeding (information gathering to inform controls)
- Biosecurity Clearance of Agricultural Compounds (compliance, understanding of and capability/competency at border).

Audits in progress

- Antibiotic Sale and Use (findings from previous sales report)
- Use of Dry Cow Therapy Products (to inform controls regarding residues)
- Imported Feed Commodities Notice (implementation)

New legal obligations for importers and manufacturers of hazardous substances

If you import or manufacture hazardous substances for any purpose other than for personal use, the Environmental Protection Authority (EPA) needs to hear from you.

New rules require importers or manufacturers of hazardous substances to provide their contact information to the EPA within 30 days of the first time you import or manufacture a hazardous substance. Even if you have been an importer or manufacturer for some time, the EPA still needs your details, which can be supplied through their online facility.

Further information about the requirements can be found on the [EPA website](#).

2015 document progress

Document	Status
Authorisation of Veterinarians	Complete
Becoming an ACVM Data Assessor	Complete
Veterinary Operating Instructions	Complete
Waiver of ACVM Fees Notice	Complete
Anthelmintics Efficacy	2nd consult closes 26/01
Bioequivalence: Vet Meds	Consult early 2016
Chemistry & Manufacturing: Vet Meds	Drafting
Exempt Agricultural Compounds Notice	Internal consultation
Fertilisers Discussion Document	Consult closes 18/12
Microbial Agricultural Chemicals	Consult early 2016
Teat Disinfectants Efficacy	Consult closes 26/01
Registration Requirements: Ag Chems	Drafting
Residue Data: Ag Chems	Consult early 2016
Risk Threshold Criteria	Consult early 2016
RVM Sellers Operating Plans	Consult closes 12/01

Performance Indicators

The following performance indicators have been proposed to enable us to set clear objectives for the registration review project. These indicators will be adjusted and confirmed as the project reaches each milestone. We are not yet in a position to meet these targets, but feel that sharing these with registrants now will indicate where we would like to be once the review has been completed and changes to the registration system are implemented.

Regulated time frames		
Application type	Percentage complete	Time (working days)
A	95%	40
B	95%	30
C*	80%	20
Notifications, renewals	95%	7-10
* working towards 95% in 15 working days and transfer of minor amendments.		

Key work streams and services (nonregulated)	
Label changes	20 working days
Deviations	30 - 40 working days
Data assessments	As agreed with applicant – Target 40 days
Provisional approvals	20 - 30 working days
Research approvals	20 - 30 working days
Acknowledge enquiries	5 working days
Confirmation app. received	5 working days
Operating plans	As agreed with applicant – Target 40 days
GMP audit reports	60 working days
Quality of assessments	< 5% decisions appealed
Adverse event report	Annually
Antimicrobial sales report	Annually

Changes in Responsibilities

Linley Thorburn, who has been with MPI for 20+ years, has resigned to pursue other interests. Her areas of work have been transferred to other team members:

- **Adverse event reports** are now managed by Awilda Baoumgren
- **Special circumstances approvals** are now directly managed by the technical team, with Jenni Doyle as the primary contact
- **Compliance issues** are now managed by Holly Jeboult-Jones
- **Border clearance enquiries and class determinations** are now managed by the Operations Team, with Maree Zinzley as the primary contact.

Send all correspondence relating to the above to:

approvals@mpi.govt.nz

Your enquiry will be transferred to the appropriate person.

New Veterinary Medicine Assessor



Justin Mercier has this to say by way of introduction:

“A little bit of my history: I was born in Tallahassee, Florida, and grew up mostly in Kansas. I began preparing for my career as a veterinarian from a very young age, and always had a fondness for biology and mathematics. I went to university at Kansas State -- eight years to get my Doctorate in Veterinary Medicine degree. After that, I worked in Ottawa, Ontario, as a small animal practitioner, doing mostly small animal medicine and surgery. I didn't care for the environment of private practice, so I went on a search to get into the public sector.

I joined MPI as a veterinarian in Verification Services in 2013, and worked at an export meat plant in Taranaki for most of the past two years. I recently got appointed as an ACVM senior adviser and made the move to Wellington. This was a big shift for me, but I am passionate about the work the ACVM Group does and I foresee a long and enjoyable career here.

I enjoy video games and snowboarding, as well as just generally lazing about the house with my wife, Emma. I also work on computers in my spare time.”

international meeting: **OECD**

Warren Hughes and Rafael Barbieri attended the Organisation for Economic Co-operation and Development (OECD) Registration Steering Group and Risk Reduction Steering Group meetings and the OECD Seminar in Brisbane, Australia, from 30 November to 4 December.

At the seminar Warren presented a paper (a case study on reassessments). At the Registration Steering Group meeting, New Zealand provided an update on the work of the Product Chemistry Employment Working Group, which we chair.

We used the opportunity of the OECD meetings being in Australia to invite our Quadrilateral Partners to New Zealand. Australia (APVMA) and the US (EPA) accepted

our invitation, and we hosted a two-day programme for them on 7 and 8 December. The New Zealand EPA also joined this meeting.

On the first day, the four agencies presented an overview of how agricultural compounds are regulated in their countries and shared years of experience in the regulatory sector. On the second day, the Australian and American delegations visited AsureQuality's Food & Contaminant Testing facility and vegetable growers in Levin. Hopefully, our visitors return to their countries with a better understanding of MPI's commitment to manage the risks associated with the use of agricultural compounds, maximise export opportunities, and improve productivity for the primary sector.

HOLIDAY CLOSURE

- The MPI office will be closed from 24 December - 4 January.
- For emergency enquiries, contact Maree Zinzley (029 894 2564).
- We will have minimal staff in the office from 5-15 January.
- Please note that the period from 20 December to 15 January is 'off the clock' as far as statutory timeframes are concerned.

Happy Holidays

We hope your holiday season is better than Santa's!

Here are a few Christmas quotes to help you through ...

*Who's the bane of Santa's life?
The elf and safety officer.*

- Catherine Tate

I once bought my kids a set of batteries for Christmas with a note on it saying, 'Toys not included'.

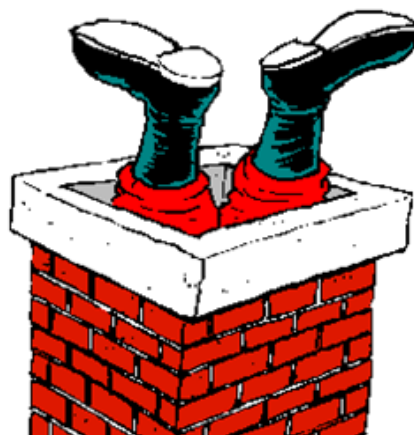
- Bernard Manning

The office Christmas party is a great opportunity to catch up with people you haven't seen for twenty minutes.

- Julius Sharpe

Santa Claus has the right idea--visit people once a year.

- Victor Borge



Christmas is a time when everybody wants his past forgotten and his present remembered.

- Unknown

What I don't like about office Christmas parties is looking for a job the next day.

- Phyllis Diller

A Christmas shopper's complaint is one of long-standing.

- Anonymous

There are three stages of man: he believes in Santa Claus; he does not believe in Santa Claus; he is Santa Claus.

- Bob Phillips

Merry Christmas to you all!