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Holiday closure information

The office will be closed from **24 December 2018 to 4 January 2019.** 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
Karen Booth (Manager) Mobile: 029 894 0544

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

Food and Live Animal Assurance
Sharon Wagener (Manager, general) Mobile: 029 894 2634
Rachel Harvie (exceptions, expert nonconformances) Mobile: 029 894 3438
Drasko Pavlovic (e-cert) Mobile: 029 909 6201

ACVM Workshop

The annual ACVM workshop will be held on Wednesday, 20 February 2019 from 8.30 - 4.30
Jet Park Airport Hotel, Mangere, Auckland.
(Note: this is BEFORE the Agcarm workshop.)

For more information and to register, go to:
https://www.eventbrite.com/e/acvm-workshop-tickets-52947985851

Please send suggestions for agenda topics to:
approvals@mpi.govt.nz
by Friday 1 February 2019.

New Zealand Food Safety
Haumaru Kai Aotearoa
Ministry for Primary Industries
Manatū Ahu Matua

Agricultural chemical compliance

Products must comply with conditions

There have been a number of incidences of non-conforming agricultural chemical trade name products including products that have been incorrectly labelled or contaminated. Both of these non-conformance types can have serious implications with regard to ACVM risk areas such as trade and crop safety.

MPI reminds 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 'Registered products' at right)
- have adequate systems and checks in place to ensure that the products sold in New Zealand meet the ACVM requirements. This applies to products manufactured in New Zealand or internationally.

Registered products

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

It also includes notifying the ACVM team of any new information such as adverse events, non-conforming product in the market and if a voluntary recall is being considered.

The conditions of registration for any trade name product can be found under that product's listing on the ACVM Register. For registrants, the conditions of registration for each product are also included with the product's Certificate of Registration.

The registrant or responsible party must take all necessary actions to ensure that the product will meet all registration conditions at all times. This includes responsibility for ensuring that overseas manufacturers or contract manufacturers are aware of all relevant conditions and specifications, and are able to provide a consistent, quality product.

Non-compliance

MPI regards non-compliance with conditions of registration as serious events, and will take action to rectify the situation.

For further information on complying with conditions of registration, see the presentation from the Feb 2018 ACVM Workshop, which can be found under ACVM Resouces on the ACVM News and Resouces page.

ACVM 101 Workshop Feedback

The ACVM team held ACVM 101 workshops on 11 and 18 October in Wellington and Auckland respectively. These workshops were to provide an introduction to the registration process. Both days were well-attended, with over 50 people participating across both events.

Thank you to those who provided feedback. Generally responses were very positive. A large majority of respondents found the workshop useful. In particular, participants commented on enjoying the interactive exercises, which gave them an opportunity to work through questions on registration problems. Stakeholders also commented on enjoying the opportunity to network and build relationships with industry participants as well as assessors. This feeling is shared by the ACVM team members who attended. It is very rewarding to meet our new registrants. Ongoing dialogue and engagement with our stakeholders is a priority for the team and vital to the quality of our work as a regulator. Several valuable suggestions and constructive criticisms were offered. These included: alternative topics for discussion, length of workshop, catering and facility choice. We will use this information to develop and plan future ACVM 101 workshops.

To conclude: the event was very interactive and its success relied heavily on participants engaging in the various exercises. Thank you to everyone for engaging willingly and cheerfully to make the day a success.

FYI

2014 - 2016 Antibiotic Sales Analysis

The final 2014 - 2016 Antibiotic Sales Analysis report was published on 28 November 2018 and can be found on the MPI website.

Maximum residue levels (MRLs)

MRL Notice
The revised Food Notice: Maximum Residue Levels for Agricultural Compounds came into effect on 5 December 2018.

MRL application form
In the past, it has sometimes been unclear how an applicant requests a change to MRLs or exemptions in the Food Notice: Maximum Residue Levels for Agricultural Compounds. The requests and supporting information received has also been variable, owing to a lack of guidance in this area. To address this, an application form has been developed to allow applicants to request changes with or without a concurrent product registration or variation application. The form allows for requests to set or amend MRLs including import MRLs, and to set or amend exemptions, and can be submitted on its own or as part of a registration/variation application. This should provide more clarity on what kind of information is required for MRL promulgation, and a more visible pathway for requests that are not specifically tied to a particular product. More detailed guidance on the data and information needed to set or change an MRL or exemption is under development.

Staff update

We have appointed a new Auditor (Regulatory Programmes), who will be announced in the next issue of *News & Views*. We are currently recruiting for:

- Assessor, Agricultural Chemicals
- Assessor, Veterinary Medicines

Approvals has appointed **Phillippa Skeet** as the Adviser replacement for Vuyisile (Vu) Mpofu, who has moved to MPI's Export Regulatory Advisory Service team. Phillippa will start early in the new year, and there will be more about her in *News & Views* once she has settled in.

Please remember that it takes time to train new staff -- your patience during this learning period is greatly appreciated.

Veterinary medicine reassessments

Two formal reassessments are currently underway.

Antimicrobial reassessment

The formal reassessment of antimicrobials from the macrolide, ketolides, third and fourth generation cephalosporin, and penicillin classes will now proceed following consultation with registrants and the finalisation of its scope.

The reassessment will be re-evaluating the approved claims and use patterns with respect to the risk of antimicrobial resistance (AMR) and whether they are still representative of good agricultural practice (GAP). The reassessment will also re-evaluate the existing maximum residue levels (MRLs) and withholding periods assigned to the active ingredients and products to ensure they reflect GAP and manage trade risk.

The registrants of the 114 affected products have been informed of the decision to proceed, and have been notified of the final scope and the data and submission expectations.

This reassessment is the first in a series of reassessments that will be proposed to review the regulation of all antimicrobial agricultural compounds as part of the MPI work plan under the New Zealand Antimicrobial Resistance Action Plan. The MRL component, which is an objective of an overarching MRL review, is being incorporated into the antimicrobial reassessment proposals as a way of limiting the regulatory burden on registrants.

The information being requested for the antimicrobial reassessment will be similar to that needed to conduct the compound-specific MRL reviews, so combining these will achieve two goals with one submission.

The team is in consultation with the affected registrants as to how long they believe they will need to compile the submissions, and the development of a time line and reassessment plan. We are currently reviewing their feedback and discussing next steps.

Reassessment of products containing decoquinate, lasalocid, and monensin

The reassessment of coccidiostat products containing decoquinate, lasalocid, and monensin for use in ruminants has been initiated to review the residue profile and MRLs applicable to these compounds.

A review of historical product-specific data held by MPI and publicly available information on these active ingredients is currently underway to determine what, if any, additional information will be required to inform the reassessment. When this is complete, registrant applications will be formally received and the reassessment will be publicly notified.

OIE AMR (Antimicrobial Resistance) Conference

Warren Hughes attended the 2nd OIE AMR Conference held in Morocco in late October 2018. In addition to about 400 participants from around the world, Ministers or Vice Ministers of Agriculture (or equivalent) from Germany, Thailand, Japan, Norway, Senegal, Botswana, Serbia, and Uzbekistan attended a question and answer session.

A number of presentations on activities to manage AMR were made by countries and international bodies such as FAO/WHO/Codex with a focus on prudent use of antimicrobials and surveillance/monitoring. There were also perspectives from industry sectors (e.g. poultry, dairy) on how they are managing AMR and some of the challenges such as private standards requiring no use of antibiotics in animals. The session on behaviour changes required by all sectors was interesting in that it explored drivers for change or no change along with communication strategies to assist in making behaviour changes.

One of the sessions outlined the lack of economic information on impacts of AMR in the animal sector both from societal and productivity perspectives. This is also an issue for New Zealand as there is limited information on impacts in food-producing animal sectors.

Class determination changes

The purpose of a class determination (CD) is to determine the status of a trade name product under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. Products that fit the definitions in this Act require registration unless they fit one of the categories exempt from registration, subject to compliance with the conditions of exemption.

The class determination (CD) request form and guideline have been updated to clarify requirements and to include the option of renewing CDs, which are valid for three years.

Changes

- Information on requirements for imported products (under the Biosecurity Act 1993 and the Hazardous Substances and New Organisms Act 1996) and for product advertising has been expanded.
- For multiple applications, we have removed the requirement to use a different form for each product type and have asked for products to be grouped by use
- The active ingredient(s) for all products must be stated.
- The applicant's obligations to comply with conditions of exemption have also been highlighted.

Renewals

In most cases, renewing a CD will be straightforward with the revised form. Applicants will only need to send us a completed form plus a copy of the previous CD letter and a copy of the label. (If changes have been made to the label, these should be highlighted on the copy submitted.)

Class determination request guideline
https://www.mpi.govt.nz/dmsdocument/12106-class-determination-request-guideline

Class determination request form (ACVM 15)
https://www.mpi.govt.nz/dmsdocument/2855-acvm-15-class-determination-request-form

Meloxicam label changes

The ACVM team has recently received human safety advice from the Ministry of Health (MoH) with regard to registered veterinary medicines that contain the active ingredient meloxicam. (Meloxicam is a non-steroidal anti-inflammatory drug [NSAID] mainly indicated to reduce the symptoms of pain caused by osteoarthritis and rheumatoid arthritis in both humans and animals.) The risks identified by MoH to humans handling veterinary products containing meloxicam include residues in food-producing animals and unintended exposure to the active ingredient when handling the product.

In order to mitigate the risk to human safety from unintended exposure, Medsafe now requires mandatory statements on the labels of all veterinary medicines that contain meloxicam. The following safe handling information must be applied to all labels as products come up for registration renewal or variation requests:

Injectable products

- People with known hypersensitivity to NSAIDs should avoid contact with meloxicam.
- Meloxicam is contraindicated in women who are pregnant. Due to the risk of accidental self-injection, women who are pregnant should not administer injectable forms of meloxicam.

Oral products

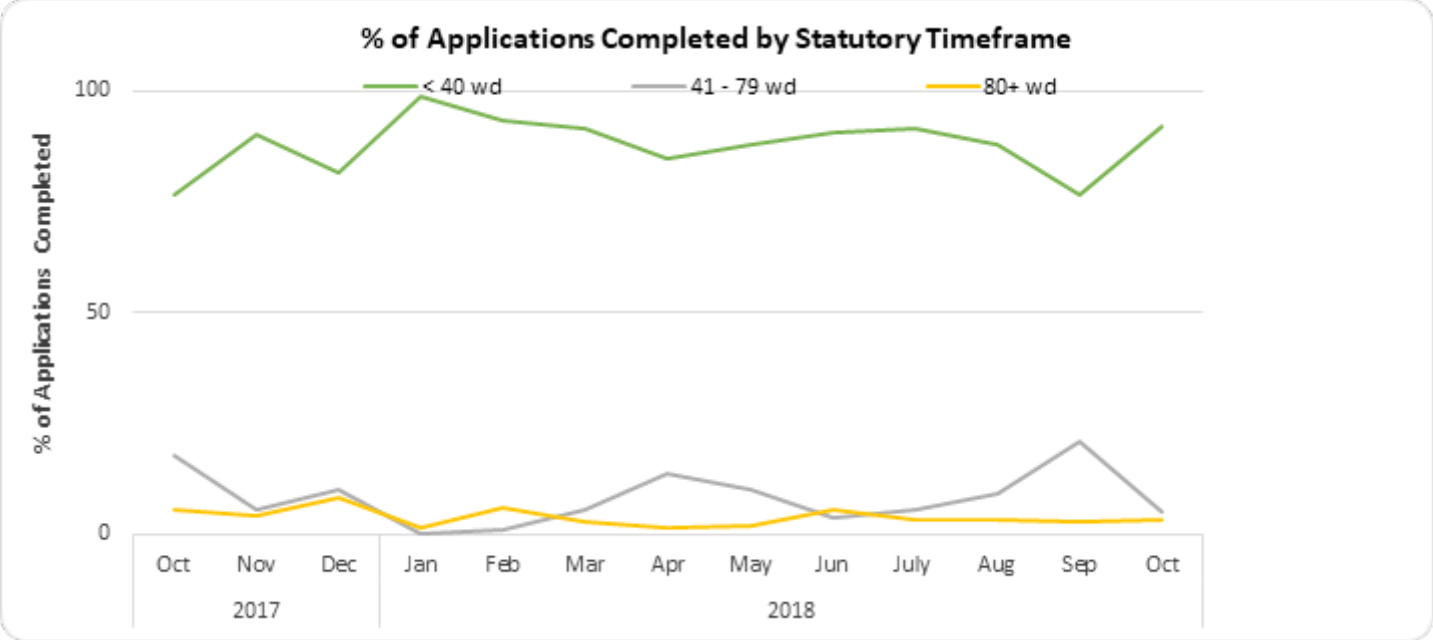
- People with known hypersensitivity to NSAIDs should avoid contact with meloxicam.
- Hands should be washed after use. If the medicine comes into contact with the skin, the affected area should be rinsed thoroughly.

Application performance statistics

In October, which is the latest month for our complete statistical analysis, application processing performance increased.

- Performance to statutory timeframe:
  - 92% of applications were completed within 40 working days, and
  - 97% were completed within 80 working days of acceptance at prescreen.
- Performance from an application arriving at MPI and registration being issued:
  - 86% of applications were completed within 40 working days, and
  - 95% within 80 working days of arriving at MPI.

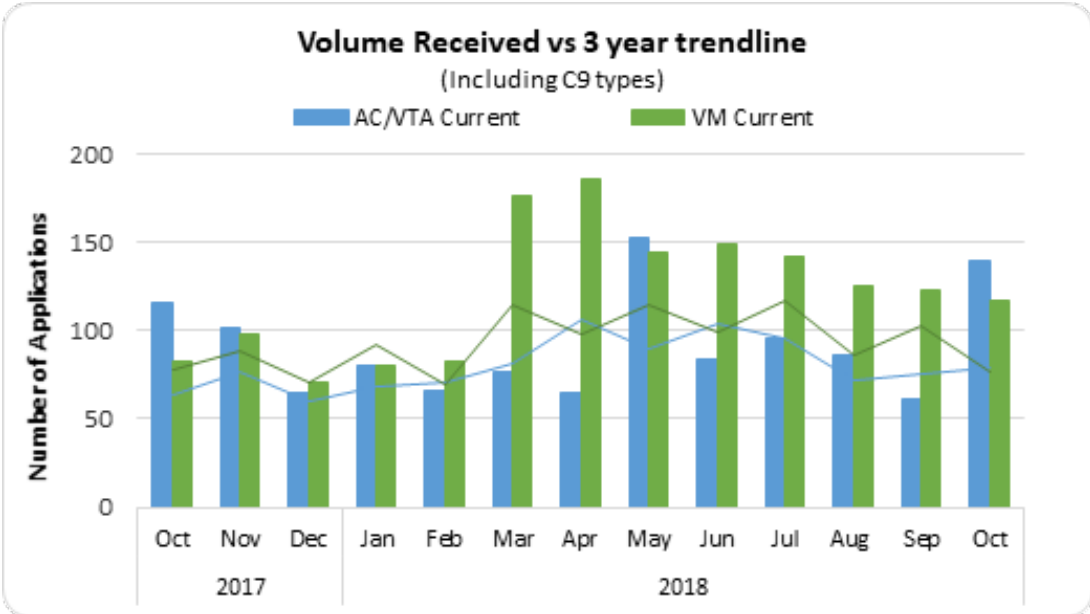
Statutory timeframes are being met for most application types (100% of administrative variations and 96% of chemistry and manufacturing variations). They were met for 45% of new product and new use applications completed in October.



Numbers of applications received have been higher than the 3-year average in recent months.

The volume of applications formally received in October 2018 was above the 3-year average:

- 140 ag chems (3-year average = 79)
- 117 vet meds (3-year average = 77)



Data protection statistics

Background

The ACVM Amendment Bill was passed by Parliament and came into force on 8 November 2016. This amendment extends the period of protection for confidential information given in support of an application to register an innovative trade name product (TNP) and also expands the scope of data protection coverage to include confidential information supplied in support of applications to register non-innovative TNPs and use.

Statistics from 8 November 2016 - 30 September 2018

Application statistics show that 4,259 applications were processed by the ACVM team in the period 8 November 2016 - 30 September 2018. As shown in the table at right, 10.6% of all applications processed were eligible for protection of confidential information (i.e. data protection).

Application Type	Number Eligible for Protection of Confidential Information	% of Total Processed (8 Nov 2016 - 30 Sep 2018)
New product registration Innovative TNPs	34	0.8
New product registration Non-innovative TNPs	230	5.4
New provisional registrations	72	1.7
New use variations	117	2.7
Total	**453**	**10.6**

Breakdown by product type

Application Type	Veterinary Medicines		Agricultural Chemicals		Vertebrate Toxic Agents		Total
	Number processed	% of total processed	Number processed	% of total processed	Number processed	% of total processed	
New product registration Innovative TNPs	23	0.54	10	0.23	1	0.02	34
New product registration Non-innovative TNPs	95	2.23	127	2.99	8	0.19	230
New provisional registrations	50	1.17	15	0.35	7	0.16	72
New use variations	54	1.27	61	1.43	2	0.05	117
Total	**222**	**5.21**	**213**	**5.00**	**18**	**0.42**	**453**

In comparison, under the previous data protection provisions, only products that contained novel active ingredient(s) were eligible (see table at right).

Year	2010	2011	2012	2013	2014	2015	2016
Number of novel active (A1) applications	24	24	25	16	13	14	18

changes to website

We have been working with the Web team to make our web pages more user-friendly. Thank you to those who provided feedback, especially on proposed changes to the pathway for finding documents. These changes have now been implemented. In the new year, the animal feeds/pet food pages will be revised and there will be new 'pages' for exempt products and veterinarians. Your input is always welcome.

Update: Transparency of applications received

Background

In 2017 MPI reviewed the level of transparency to the general public and stakeholders of the current trade name product registration procedures and processes managed under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. The review was prompted by:

- the New Zealand government policy directive of Open and Transparent Government
- management of, and provision of, information in response to Official Information Act 1982 (OIA) requests
- awareness of differences in the level of disclosure of registration application information by comparable regulatory authorities (European Medicines Agency [EMA], US Food and Drug Administration [FDA], Australian Pesticides and Veterinary Medicines Authority [APVMA]), and
- increasing focus on providing an appropriate level of information about the registration of ACVMs to the New Zealand general public and primary industry sectors to support a robust decision-making process.

Proposed changes

MPI proposed to improve the transparency of the registration process with the following three changes, which were explained in the public discussion document Transparency and ACVM Registration Applications:

- creating an 'applications received' report that would be published regularly on the MPI website
- changing the information provided on the Public Record of the Delegate Decision document that appears on the ACVM Register of Trade Name Products, and
- requiring applicants to provide a summary listing of the information provided with their application.

Feedback requested

MPI requested feedback on the proposals, particularly on these questions:

1. Is the level of transparency and disclosure appropriate?
2. Is the proposed categorical description of information provided by an applicant in an application suitable?
3. Is the proposed information on aspects considered in an application, and risk management outcomes stated in the Public Record of Delegate Decision appropriate?
4. Are there any other areas of the ACVM product registration process that require more (or less) transparency?

Public consultation on this document closed 16 March 2018. MPI received six submissions: three from companies and three from organisations representing industry sectors. Five of the six submissions generally supported the intent behind the proposals. Four of the five asked for clarifications and expressed some concerns. One submission was strongly opposed to the proposed changes.

ACVM actions

The ACVM team is considering how best, with existing IT and reporting systems, to provide the appropriate level of transparency without increasing the internal administrative workload.

Agcarm Field Trip

In November, Agcarm hosted a field trip to the Wairarapa and several ACVM Assessors were able to attend. The trip included stops at an agricultural chemical manufacturer, a veterinary clinic, a rural supplies store, arable and sheep and beef farms, as well as a winery. The visits provided useful context of the industry outside the regulatory process. Registrants and stakeholders visited outlined the commercial imperatives that drive their business. In particular, they highlighted how the regulatory process fits into their planning and risk allocation. The team appreciates this valuable opportunity provided by Agcarm to interact directly with our stakeholders.

Food & Live Animal Assurance Team Update

Export Approved Premises Notice

The Export Approved Premises Notice has recently been updated. The changes mainly relate to germplasm and live poultry export premises. Changes include:

- requirement that germplasm and live poultry Export Approved Premises (EAP) be associated with a veterinarian
- requirement to have approved standard operating procedures (SOPs), and
- allowance for disease compartments.

The Notice template has also been updated so it is consistent with the format of other Notices.

CCFICS meeting

Ann Oliver attended the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) meeting, which was held in Brisbane in October 2018.

Main items of interest were:

- guidelines on the use of systems equivalency
- paperless use of electronic certificates, and
- the use of Third Party Assurance Schemes.

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happy holidays

Best wishes to you all for a safe and relaxing holiday season.

The Assurance Directorate