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ACVM News & Views

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In this issue:

Data Protection

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 provided in support of applications to register non-innovative TNPs and use.

The updated ACVM Act can be found on the New Zealand legislation website. Information for applicants is available on the MPI website.

When you submit an application for registration, you must apply for any required data protection using this form: Identification of Confidential Information for the Purpose of Data Protection

We are preparing industry guidance material and will present this to registrants during the February workshop (see box below).

Earthquake disruption

Following the massive Kaikoura quake, the Wellington MPI office was closed for 3 days until the structural 'all clear' could be given. In addition, the Operations Team (and all other staff located on the top 2 floors of the building) were re-located for 2 weeks while additional safety measures were installed on Levels 17 and 18.

As a result of these disruptions, 'business as usual' has been anything but. We ask you to be patient as we work through applications during our busiest time of year.

ACVM Workshop

Sudima Hotel, Auckland
23 February 2017
(following Agcarm Conference)

Focus: Registration review outcomes and data protection

Detailed information will be available late January.

Register interest: approvals@mpi.govt.nz

Ministry for Primary Industries
Manatū Ahu Matua

Registration Review Project Update

The Registration Review Project team advises the following process initiatives are being developed and tested internally. These have been communicated to both Agcarm and ARPPA via consultation meetings in November and December 2016. Feedback is always welcome.

Registraton renewal process
Review of the registration renewal process has been completed and we plan to change the default registration expiry period from 3 years to 5 years.

An implementation plan has been developed and is pending sign off. The plan includes internal and external facing requirements such as communication tools, forms, templates, and guidance materials.

Paperless process initiative
The recent Kaikoura earthquake has reaffirmed the need for a paperless registration process that potentially can be run remotely by MPI staff.

ACVM staff have been trialling a digital process flow. Issues identified during this process are being worked through.

Product and manufacturing specs
The work on how product and manufacturing specifications are defined and captured as part of the registration process is ongoing.

We are proposing to strengthen the product identity characteristics, and manufacturing and quality characteristics that define a trade name product. Better information in the product and manufacturing specifications will act as a more effective point of reference when variations are made, and for purposes of auditing and compliance. Importantly, this will also inform the development of guidance to applicants and pathways for the management of applications for specifications changes to registrations.

Screening of applications
We are proposing to be more rigorous in the screening of applications prior to official receipt. Efficiency of the registration process to date has been negatively impacted by acceptance of applications that are found later to be inadequate or insufficient.

Transparency
We are still looking at cost effective ways to improve transparency around applications received, as well as applications approved. The intent is to provide more information for interested and affected parties while preserving protection of commercially sensitive information.

FAO Pesticide Registration Toolkit

The Pesticide Registration Toolkit is a decision supporting system coordinated by the Food and Agriculture Organization (FAO). It provides support to several regulatory tasks, including:

- finding data requirements
- evaluating technical aspects of the registration dossier
- choosing an appropriate pesticide registration strategy and procedures
- reviewing risk mitigation measures, and
- getting advice on decision making.

The Toolkit also links to pesticide-specific information sources such as registrations in other countries, scientific reviews, hazard classifications, product labels, MRLs and pesticide properties.

The FAO has planned the roll out of this project and prepared a pool of specialists who will deliver national or regional training on the use of the Toolkit. Given the strong cultural, economic and political links between New Zealand and the Pacific Islands, and the formal connections between New Zealand and Southeast Asia, MPI's ACVM Group was invited to assist with the training and capacity building of pesticide registration authorities in these regions.

From 7 - 18 November, FAO hosted a training-of-trainers workshop on the Pesticide Registration Toolkit. Rafael Barbieri attended this meeting and will actively engage in the roll out of the Toolkit in the Pacific and Southeast Asia in 2017.

FAO Pesticide Registration Toolkit website:
http://www.fao.org/pesticide-registration-toolkit/en/

FYI

Alignment of ACVM and Biosecurity assessments

MPI Animal Imports and ACVM are well on the way to aligning ACVM registration and biosecurity clearance applications. The aim is that applicants who need to apply for both will only need to fill in one form. We will test the new procedure with a few registrants early in the new year. All going well, we hope to have the alignment up and running by the middle of 2017.

VCNZ Code of Professional Conduct

MPI will meet with the Veterinary Council of New Zealand (VCNZ) as part of a working group to review the veterinary medicines section of the veterinarian's *Code of Professional Conduct.*

The working group will focus on the way restricted veterinary medicine (RVM) authorisations are managed in the Code, including those authorisations associated with annual consultations, as well as prudent use, record keeping, product management, and product stewardship.

Antimicrobial resistance

MPI's antimicrobial resistance (AMR) work programme has commenced. The programme includes the establishment of prudent use guidance, a review of the existing controls, reassessment and surveillance and monitoring activities.

Anticoagulant vertebrate toxins review

A survey of the registration conditions applied to anticoagulant products has been completed and progress is being made on a paper summarising the risks and options arising from this data. Note that while this work progresses MPI may commence re-assessments of some products, dependent on the suitability of current controls.

FYI continued

MRL Notice

The last round of maximum residue levels (MRLs) was issued on 20 October 2016.

The next round of MRLs is currently being drafted. This round of MRL promulgations will include the reduced MRLs for organophosphates and carbamates from the OPC reassessment. The draft for consultation will cover:

- new and amended MRLs for 32 compounds
- 2 new exceptions from MRLs for agricultural chemicals
- 3 amended residue definitions.

The draft promulgation proposal is expected to be completed and released for comment early in the new year.

Residues of veterinary drugs in food

The VICH GL 54 (Safety- Acute Reference Dose (ARfD)) – Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD) will be posted onto the VICH website. John Reeve from MPI was our ANZ Observer representative on this.

Toxicology Training

Agricultural compounds adviser Rafael Barbieri recently attended some modules of the Dutch National Programme for Vocational Postgraduate Training in Toxicology. The modules, which correlated with areas of interest to the ACVM Group, were:

- General Toxicology
- Risk Assessment in Toxicology
- Legal & Regulatory Toxicology

We currently do not have designated resource in toxicology and rely heavily on the MPI Science Risk Assessment Directorate toxicologists for core service. This has impacted application processing time. We plan to continue to invest time and resource to this area.

2016 documents update

Documents	Status
Microbial Agricultural Chemicals	Complete
Operating Plans for RVM Sellers	Complete
Risk Management under the ACVM Act	Complete
Post-ACVM Authorisation Risk Mgmt	Complete
Teat Disinfectants Efficacy	Complete
Anthelmintics Efficacy	Finalising
Bioequivalence: Veterinary Medicines	Finalising
Chemistry & Manufacturing: Veterinary Medicines	Revising after consultation
Exempt Agricultural Compounds Notice	Consult early 2017
Residue Data: Agricultural Chemicals	Consult early 2017
Compounding Veterinary Preparations	Internal consult January
Registration Requirements for Trade Name Products	Drafting

Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)

Houston, Texas, USA: 16-21 October 2016

The New Zealand proposal to include monepantel on the priority list for cattle MRLs was accepted at this meeting.

Other items of interest were:

- The risk management recommendation for gentian violet was moved to step 5, but with objections from New Zealand and other countries.
- MRLs for ivermectin, lasalocid sodium, and teflubenzuron were progressed.
- It was decided that the issues around the unavoidable and unintended residues of approved veterinary drugs in foods resulting from carry-over of veterinary drug residues in feed would be put on hold while awaiting the outcome of the FAO/WHO scientific advice on this matter.
- An environmental working group (EWG) was formed, to be chaired by Kenya, to further discuss the potential issues associated with higher residues being found in certain offal types not traditionally considered edible.
- There was considerable discussion on the lack of proposals for MRLs and whether the committee should continue. New Zealand considers the work important, but if there is lack of MRLs then the continuation of the committee needs to be considered. In the meantime, we will actively engage with New Zealand manufacturers on sponsoring MRLs for the committee.

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

Hoping you have a happy, safe, relaxing holiday season!

Best wishes from all of us at ACVM

HOLIDAY CLOSURE

The MPI office will be closed from 24 December - 4 January. For emergency enquiries, contact Glen Bradbury (glen.bradbury@mpi.govt.nz) We will have minimal staff in the office from 4 - 9 January.

Please note that the period from 20 December to 15 January is 'off the clock' as far as statutory timeframes are concerned.