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# ACVM News & Views

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## Workshop for Registrants Exceeds our Expectations

The ACVM workshop for registrants held in Auckland on 25 February 2016 had more participants than ever before. Ninety people registered and 106 attended.

Several team members gave presentations covering:

- ACVM Group overview and update
- our expectations of registrants
- pre-screen
- registration review project
- reassessments
- changes to the MRL setting process
- ACVM Amendment Bill.

The industry was particularly happy to hear about the ACVM Amendment Bill (data protection) and the ongoing process review.

On the agricultural chemicals side, participants provided positive comments on the guidance document for registration of Microbial Agricultural Chemicals (open public consultation) and the outcomes of the proposed changes to regulatory oversight of fertilisers and fertiliser additives (see more on page 3).

Points of criticism were mostly related to lack of clarity in current guidance documents and the EPA-ACVM interface.

These points were noted and we will:

- work to improve clarity of our guidance documents, and
- work with EPA to avoid problems that could potentially create a conflict or delay the registration process.

Thanks to all who participated in the workshop. We received good feedback and several requests to make the PowerPoint presentations available on our website. This has been done (as a pdf file).

**Next workshop**

Send us your ideas on how we could improve our next workshop, and we have a request to make of anyone who plans to attend. Please register ahead of time so conference organisers and caterers can assess our room/food needs accurately.

## Transition to an MRL Notice Requires Label Change

**The Food Act 2014 came into effect on 1 March 2016, and MRLs in food are now specified under the Food Notice: Maximum Residue Levels for Agricultural Compounds.**

**If you have a product that this affects, then the relevant condition on your product will be updated automatically on the public website to reflect the name of the Food Notice.**

**However, you will need to update the associated regulatory statement on labels to "It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels for Agricultural Compounds" at the next label change or registration renewal.**

**If this is going to cause a significant issue for you, please contact us as soon as possible (approvals@mpi.govt.nz).**

Ministry for Primary Industries
Manatū Ahu Matua

# Oral Nutritional Compounds (ONCs) Exemption Requirements

***MPI has become aware that not all ONC manufacturers are complying with the requirements for exemption in the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011.***

Substances composed of nutrients and intended to provide a nutritional benefit that are fed to animals are considered ONCs. They are exempt from registration as long as they do not claim:

- to prevent, control, or cure a specific disease characterised by pain or distress in animals
- to have pharmacological or anabolic effects, or
- to modify the physiological function of an animal.

The conditions of the exemption are stated in Schedule 2 (Agricultural compounds exempt from registration) of the regulations.

**Registration required if ingredients give pharmacological effect**

If an ingredient is usually considered a nutritional supplement but is known to have a pharmacological effect in an animal at a specific dose rate, inclusion of the supplement at the pharmacological dose rate means the product is NOT exempt from registration. This also applies to products that contain an ingredient that is known to have a pharmacological effect but do not specifically make claims to treat, prevent, or cure a disease. ONCs that contain ingredients that give a pharmacological effect must be registered under the Agricultural Compounds and Veterinary Medicines Act 1997.

**Incorporating trade name products**

ONCs can incorporate a trade name product to produce a medicated ONC, such as a calf milk replacer containing a coccidiostat, or feed supplemented with therapeutic nutrients like Zinc. This can only occur if:

1. the added trade name product is registered under the ACVM Act; and
2. the incorporation of the registered trade name product is consistent with the conditions of its registration.

**Labelling and advertising requirements**

To be considered consistent with the trade name product's registration conditions the efficacy claims, target and class of species (e.g. calves, lactating cows), dose rates, and withholding periods approved for the registered trade name product MUST be included on the ONC labelling. The manufacturer must also ensure that the medicated ONC is formulated to deliver the registered product at the approved dose rate when fed to the animal. Any warning statements or contraindications (such as "Ingestion by dogs and horses has been fatal") must be included on the ONC label.

In addition, the registered trade name product must be approved for use in the intended ONC and must be administered as per the approved product label (e.g. the product is formulated for inclusion in grain feed and is being used as such). All required regulatory information (registered trade name, registration number, and any applicable regulatory statements) must be included on the label. These requirements are not met by simply stating that "This product contains X brand name".

All advertising including product labelling for ONCs that include a registered veterinary medicine (i.e. a medicated feed) must clearly state the full registered trade name of the product incorporated into the ONC and the registration information (the statement from the product label that reads "PRODUCT XX is registered pursuant to the ACVM Act, Registration No. AXXXXXX" or similar).

In addition, the advertising and product labelling must state the quantity/ concentration of the veterinary medicine in the feed and the feeding rates, which must be as per the approved label dose rates for the registered product.

Knowingly selling an unregistered ONC that is not compliant with the conditions set out in the ACVM (Exemptions and Prohibited Substances) Regulations 2011 is an offence under the ACVM Act.

If you are unsure if your product requires registration, submit a request for a class determination to the ACVM team.

## *Dichlorvos reassessment*

**The Environmental Protection Authority (EPA)'s recent reassessment of some dichlorvos products resulted in the reduction of the Acceptable Daily Intake (ADI).**

**We are reviewing the approved uses of trade name products containing dichlorvos to ensure that the uses are still current and that the new ADI will not be exceeded.**

# FYI: Consultations

## Fertiliser regulatory options

Public consultation on *Proposed changes to regulatory oversight of fertilisers and fertiliser additives* (MPI Discussion Paper 2015/39) closed in December 2015. We received 17 submissions from a range of organisations. We have been working through the submissions, which presented diverse views on the options proposed as well as alternative options. There was no clear outcome, so we propose to meet with submitters to hold a joint discussion. We hope to get a clearer understanding of the wide-ranging views presented.

## Operating plans for RVM sellers

Consultation on this guidance document closed in January. Following review of the four submissions received, some adjustments have been made to the guidelines. The final document and the revised template for the operating plan will be available soon. Subscribers to the ACVM website content will be notified when the documents have been uploaded.

## Teat disinfectants

We received ten submissions during consultation on the registration information requirements for efficacy of teat disinfectants. The submissions have been reviewed and a final draft of the document is close to completion.

## Anthelmintics

Consultation on the registration information requirements for efficacy of anthelmintics (cattle, sheep, goats and deer) produced six submissions. We have considered the points raised in the submissions and are preparing the final draft of the document.

## Microbial agricultural chemicals

Consultation on the information required to register a microbial agricultural chemical closed on 24 March. The submissions received will be reviewed during April.

# Requirements for Sellers of Restricted Veterinary Medicines

An article in the September 2015 issue of *ACVM News and Views* explained that MPI has amended the conditions of registration of restricted veterinary medicines (RVMs) to give effect to the recognition of veterinarians to authorise the purchase and use of RVMs.

**Background**
In August MPI re-issued its recognition (now under section 44G of the ACVM Act) of veterinarians to authorise the purchase and use of RVMs and issued the ACVM Notice: Requirements for Authorising Veterinarians. This notice is a restatement (without material change) of the performance and technical standards issued under the now repealed section 62 of the ACVM Act. At the same time, MPI also issued *Veterinary Operating Instructions* to provide guidance about authorising RVMs that will be held by the user for a later, anticipated need.

With authorisation of purchase and use on a sound regulatory footing, we turned our attention to reviewing regulatory control over selling/supplying RVMs.

**Operating plans for RVM sellers**
In order to comply with the sale condition imposed on the registration of all RVMs, a seller must have and comply with an operating plan approved by MPI under section 28 of the ACVM Act.

To provide clear guidance to sellers on how to develop an operating plan that will meet MPI requirements, we have updated *Expectations of RVM Sellers* in consultation with sellers and veterinarians. The new guidance document, *Approval of Operating Plans for Sellers of Restricted Veterinary Medicines, (*and a revised operating plan template) will be issued soon.

**Supplying RVMs**
In the meantime, we remind sellers of their obligations when supplying RVMs.

When supplying RVMs to other sellers, the seller must:
- ensure that the buyer has an approved operating plan to sell RVMs, and
- control all aspects of storage, dispatch and distribution until the RVMs are in the hands of the legitimate buyer.

When supplying RVMs directly to the end user, the seller must:
- verify the essential details of the authorisation to purchase and use an RVM
- provide essential information concerning the identity of the seller, the authorising veterinarian, the RVM itself, and the authorising veterinarian's instructions, and
- control all aspects of storage, preparation, dispatch and distribution until the RVMs are in the hands of the person specified in the authorisation.

Sellers and authorising veterinarians have to work together to make sure that RVMs are only supplied to authorised persons.

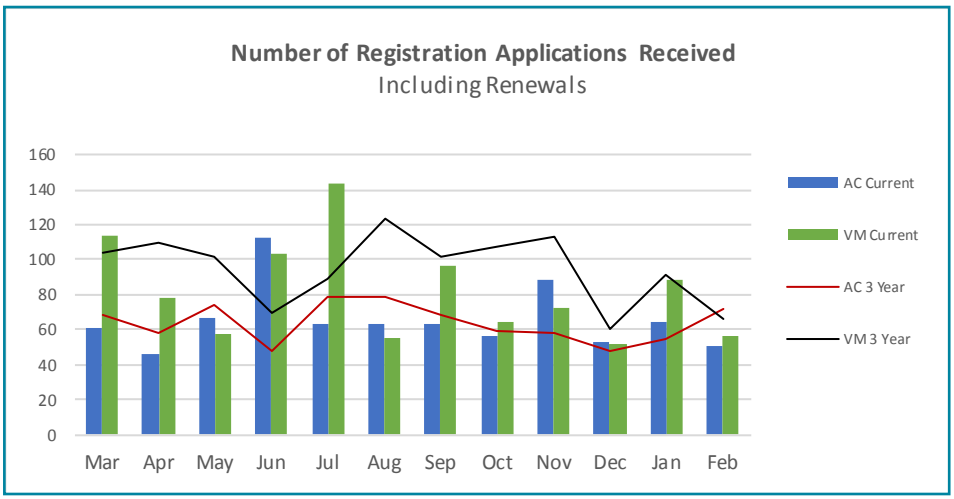
## Importers and manufacturers register with EPA

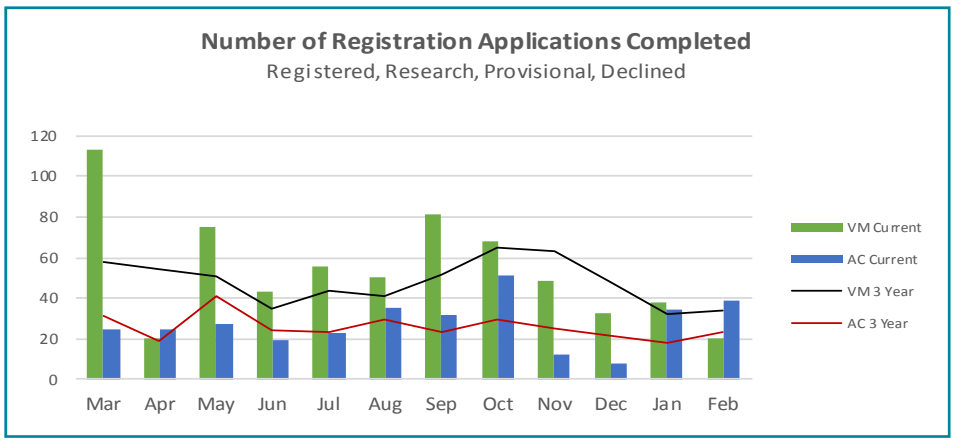
Over 500 importers and manufacturers of hazardous substances have already registered their details with the Environmental Protection Authority (EPA).
Under new rules brought in on 19 November 2015 anyone who imports or manufactures hazardous substances for any purpose other than for personal use must register their details with the EPA within 30 days of first importing or manufacturing a hazardous substance.

Even if you have been an importer and manufacturer for some time the EPA will still need your details. There is an online facility on the EPA's website to make supplying business details and contact information easy and fast.

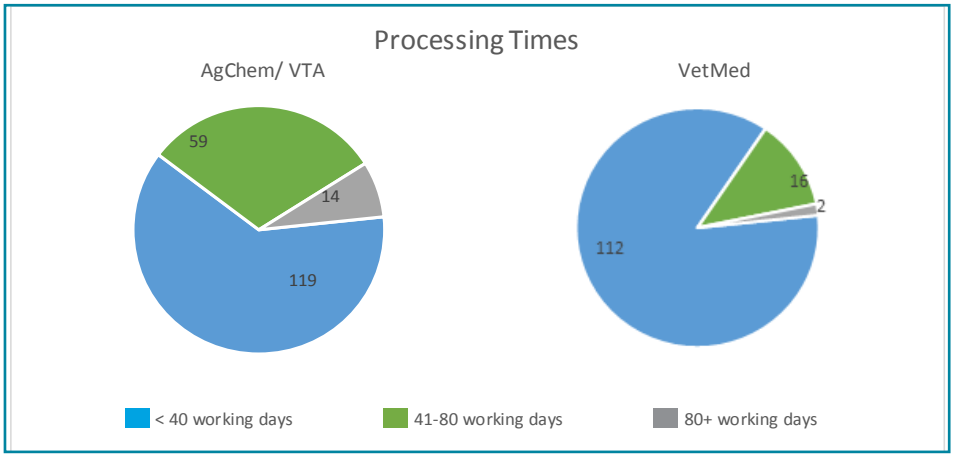
# applications update

Applications for registration received and numbers completed for the past 12 months are compared with the respective averages over the past three years in the graphs below.




The pie charts below show processing times for applications completed over the past three months. The number of days is the total time taken, with time waiver periods not removed from the figures. Note that many AgChem and VTA applications are taking up to 12 weeks longer than the optimal timeframe. We have addressed this with the employment of additional contract staff, and you should already have started to see a reduction in timeframes for simpler applications as a result.




**If you are sending us an Adverse Event Report, please use this new, dedicated email address: ACVM-AdverseEvents@mpi.govt.nz**

## New EPA 'Status of Substance' process

The Environmental Protection Authority (EPA) is improving the process for finding out if a hazardous substance is already approved for import or manufacture in New Zealand.

### Importing or manufacturing hazardous substances

To import or make a hazardous substance you need an approval from the EPA. Because there are already approvals covering thousands of different substances and formulations, it's often possible to match your substance to one of these approvals.

The EPA currently offers a 'Status of Substance' (SoS) service that provides informal advice about whether products fit one of these existing approvals.

### New statutory process

This current advisory process is being replaced with a new statutory one, which is part of the government's simplification of the regime for managing hazardous substances. From 1 July 2016 the new service will provide a formal, legally binding and notified decision.

The statutory process will provide a legal determination about a substance – giving certainty about its status, HSNO classification and whether it matches an existing approval. This will make it easier to be sure of complying with the HSNO Act.

### Transition period

To manage the change there will be a transition period from 1 April through 30 June. From 5pm on 31 March the EPA won't accept any new requests and will return any requests awaiting more information, unresolved, by 30 April 2016.

During the transition you will still be able to get a formal determination about whether a substance is hazardous and you can still 'self-assign' (there are instructions for this on the EPA website).

For more help contact the EPA on: sos@epa.govt.nz