ACVM

Ministry for Primary Industries
Manatū Ahu Matua

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Public notification of all new registration applications

Under the ACVM Act all applications for registration and variations to registrations must be publicly notified (section 14) unless MPI agrees to waive this requirement (section 15). In the past, MPI waived public notification for applications if the risk profile was not significantly different to products already on the market.

However, as we advised attendees of the February ACVM workshop, our intention is to publicly notify all new (that is, A1, A2, B1 and B2) applications for registration. (MPI may decide to extend this to variation [C type] applications at a later date.)

The proposal is to notify new applications received on a weekly basis on the MPI website. Likely details in the notification will include the trade name, applicant, active ingredient(s), product type and summary of proposed uses. Any person can subscribe to the ACVM part of the website to receive an email notification.

This change is in response to a number of industry sectors wanting to know what products are being considered by MPI for registration. The information will assist them in assessing the impacts (both positive and negative) on their industry sector.

If you have any comments on this proposal, please send them to us by **30 April 2014** (approvals@mpi.govt.nz).

Imported feed commodities

The final version of the ACVM (Imported Feed Commodities) Notice 2014 has been signed by MPI Director-General Martyn Dunne.

This notice, which applies to all persons importing feed commodities into New Zealand for animal consumption and all persons involved in the manufacture of feed commodities for sale on the domestic market, will come into force in three stages (21 April 2014, 21 August 2014 and 21 January 2015). 'Commencement' on page 1 of the notice provides details of the implementation.

For background, see the February 2014 issue of *News and Views*.

Annual fees heads up for registrants

The annual fees process will start in May when you will receive letters:

- advising you to check your registered products on the website register
- explaining the de-registration process if you no longer wish to market products
- asking for any address changes for posting invoices.

Compliance update: Trade Me

ACVM and Environmental Protection Authority (EPA) staff recently met with Trade Me Trust and Safety staff members to discuss Trade Me members selling decanted agricultural chemicals in unapproved pack sizes.

Investigation showed that a very low number of agricultural chemicals had been sold on Trade Me, and the small number of non-compliant sellers had their listings removed from the site.

We remind ALL registrants to keep a watching brief on Trade Me for anyone selling non-compliant agricultural chemicals and veterinary medicines. If you believe a Trade Me member is selling a non-compliant product, contact trustandsafety@trademe.conz. Please also notify us so we can monitor the situation.

ACVM workshop questions and answers

The following series of questions and answers were from the ACVM workshop held 27 February 2014. Although many of these questions were printed in the News and Views *coverage from last year's workshops, we believe it is worth repeating them for all the 'new players' in the industry.*

Confidential Supporting Information (CSI) (aka data protection) under the ACVM Act

How does EPA data protection work?
There are no CSI provisions under the Hazardous Substances and New Organisms (HNSO) Act 1996. Rather the Act references this to CSI provisions under the ACVM Act. This means eligibility for CSI protection for part 5 approvals under the HNSO Act requires the applicant to apply for the product's registration under the ACVM Act first (or at the same time).

Does the EPA give data protection for research approvals?
No. Research approvals are not covered under the CSI provisions of the ACVM Act.

Is the EPA looking at establishing data protection rules under the HSNO Act?
We cannot comment on this.

Are products exempt from registration eligible for data protection?
No. CSI protection is only for products requiring registration under the ACVM Act.

Is new information on an existing active ingredient (such as data on a new use, claim or application rate) eligible for data protection?
Currently, once the CSI protection period has expired for a product there is no further protection period for additional claims etc. The Government has agreed to amend the CSI provisions in the ACVM Act to provide for extra CSI protection under this scenario.

Application statistics

Aren't some applications more work than others?
Yes. The level of work varies considerably between applications, even applications of the same type. This is due to a number of factors including the complexity of the application, quality of the submission and policy implications.

If there was a net increase in applications and increases in all three product categories (Veterinary Medicines, Agricultural Chemicals and Vertebrate Toxic Agents), aren't there more fees coming in and therefore more money for additional resource?
Yes, in theory the more applications received means more fees. However, charging is based on an hourly rate so making gains on income from fees means staff members have to be working on applications. This is not always the case, particularly in recent times with staff being diverted to non-charging areas of work such as compliance and responses. In addition, MPI needs to review its cost recovery including in the ACVM area (such as the hourly rate) to ensure we are recovering the correct amount.

There are over 3,000 products registered so roughly 1,000 products a year need to be renewed, which is a lot of work for registrants and for ACVM. Will you consider extending registration to greater than 3 years?
Yes, in theory. However, a number of registrants make regular changes to their product registrations and when the change is approved, the registration receives another 3 years. (Some follow-up statistics on this after the workshop indicate around 85% of products registered have changes made to them prior to having to renew their registration.) In stating this, we will be considering whether the registration renewal period could be extended say to 5 years and, if so, under what circumstances would this be acceptable.

Application process and label requirements

What is the preferred format for electronic submissions?
Details on this can be found on our website at:
http://www.foodsafety.govt.nz/elibrary/industry/guideline-for-efiles-acvm-applications.pdf.

Is there any future plan for setting up a secure email for submissions?
We are investigating this and working with our IT department, bearing in mind our system must comply with any requirements across Government departments.

For variations to products for which there is a market label, how do we submit a tracked changes version without using Word drafts?
You can highlight a hard copy and scan it in for submission, or track changes in Word if there is no final market label yet (that is, the draft version is still the current version).

Are you no longer accepting draft copies of labels at registration renewal?
Yes, this is correct. It has been 3 years so we expect a market label in the market place. We are updating our public register to show the market label, rather than a Word document version. We are proposing that registrants submit a PDF of the final marketed version. Please note that the final market label can either be the final approved copy prior to printing (that is, the label approved by the registrant for printing) or the actual printed label.

It is very difficult to read some of the PDF labels on the Public Register, and file sizes are large. How do you propose to manage these issues if all the labels are meant to be final marketed labels?
We realise there may be issues that still need to be addressed with regards to file size and

legibility of marketed labels. We will continue to accept both PDFs and Word documents of the final approved label in the interim while we develop IT solutions to these problems.

If we have labels where the artwork will be changing, can we send a draft label then follow it up with the final artwork?
Yes, that is the current rule. However, a registrant failing to follow up and send the market labels is part of the reason why the ACVM register is out of date. We prefer that the final market label is submitted with the application/renewal.

Food clearance (maximum residue limits)

Is there any plan to consider setting MRLs in line with Australia?
No. The main reason is that good agricultural practice can differ between the two countries, so MRLs may need to be different. However, under the Trans Tasman Mutual Recognition Agreement, food commodities traded between the two countries may comply with either country's MRLs.

Recognition of data assessors

How will we know who to use for data assessment with respect to expertise in the field?
Once data assessors are recognised, they will be placed on our website with details of the scope of their recognition.

Will there be an obligation to engage only a recognised data assessor?
Yes. This is our proposal to ensure data assessment is done by a person with the appropriate competency and expertise. It will also encourage persons to become recognised.

What is the timeframe in which this will be implemented?
Our intention is to implement this over the next 3-6 months.

What is the recognition process? Currently acceptance or decline of a data assessment is subjectively performed by technical assessors who are not as knowledgeable as the industry.
Recognition of data assessors is within the context of an ACVM data assessment. Key elements of this are understanding of the legislation and the ACVM Information Requirements, and expertise of data assessors. We have access to a wide range of technical expertise to assist us in areas where our knowledge may be limited.

If a data assessor goes on to work for a registrant company, does that mean that data assessor will be de-recognised?
New Zealand is a small country and in some areas the number of persons with the appropriate knowledge and expertise is limited. We would expect a data assessor to declare any conflicts of interest. If a conflict of interest can be managed or mitigated, the data assessor may not need to be de-recognised or excluded from doing a particular data assessment. Requirements will be outlined in the data assessment guidelines, and conflict of interest will be looked at on a case by case basis.

When is data assessment required? Is there a guideline?
There is no guideline on this. While we consider most instances when and under what circumstances a data assessment is necessary are self-evident, we will investigate the need to develop a guideline. In the meantime, if a registrant has any doubt they should contact us for advice on whether data assessment is required for a particular set of data.

Adverse event reporting (AER)

You have said that products will be grouped by active to preserve confidentiality of the trade name product/company. What about products where there is only one trade name product with a particular active?
Adverse event reporting by active is an internationally used method and MPI's proposed method is very similar to the reporting method adopted by APVMA. It would be inappropriate to use an alternative method as it is important that MPI remains transparent in reporting all adverse events that are related to a product that contains the specified active.

While it's good that the adverse events are being reviewed more closely, stating there are four AERs for abamectin in cattle does not provide context. The number of animals treated (4 out of 4, or 4 out of 4,000) and animal class (age, weight, type – dairy vs beef) to qualify reactions would make this information more useful.
The details to be included in the report have not yet been finalised. However, the objective of the report is to report only the possible and probable adverse events for each product listed by active. It is not the intention of the report to include any information that can be interpreted subjectively. Any trend analysis that MPI uses to assess the impact of adverse events will consider the actual incident level if this is relevant to the adverse event.

The current guidelines are not sufficiently clear for agricultural chemical registrants. Will they be updated?
We are willing to look at making changes as there is a degree of subjectivity. To assist us, we encourage registrants to make submissions on specific areas in the guidelines that need further clarification.

Deviations for information requirements

I know there is no regulatory timeframe for deviations. What is the internal timeframe that the assessors work to?
The target for completion of deviation applications is 3 months, but it is dependent on the quality of the application, the deviation being requested, and the current workload. Applications for which a regulatory timeframe applies must take precedence over those that do not have a timeframe. We are also working on improving tracking and visibility of the deviations workload.

Class determination

Can a reminder be sent out when class determinations are due to expire like we get for registration renewal?
No. This is the responsibility of the importer/manufacturer.

RTTOs

Would ACVM be able to provide better clarity on timeframes for processing RTTO applications?
We will look at establishing a general timeframe once we have sufficient information to inform this. In the interim we will notify applicants of the estimated time on acceptance of an application.

Processing of RTTO applications appears to be inconsistent within ACVM
We recognise consistency is very important in processing all application types. As the RTTO process is new, there is a settling in period for processing and there may be some inconsistency initially. Internal procedures along with peer review will lead to more consistency in the future.

Veterinary Medicine Session

Registration by reference

Why is it that when data is submitted which was accepted by the APVMA that the same approval/shelf life/claim is not approved by ACVM?
When registration by reference was established, it was determined that the risk assessment principles were similar enough between the ACVM and the APVMA to allow data sharing and the use of APVMA assessment in lieu of data assessment. However, the risk management strategies that come from this assessment are reflective of the regulating country's individual practices, risks and legislation. The outcomes and approvals can therefore vary in some cases despite using the same data for risk assessment. The New Zealand/Australia agreement for registration by reference is currently under review.

Is data sharing reciprocal?
Not at this stage, but we are working with Australia with the intent of enabling this to happen.

What is the timeframe for registration by reference? There appears to be a longer delay from submission to approval when compared to a standard submission.
The APVMA assessment documents are needed before the application can be screened for acceptance for assessment by ACVM. The process of requesting and receiving this information can sometimes be delayed because it relies on the ability of APVMA to provide the information--there is no timeframe for this in the MOU. Once accepted for appraisal by ACVM, the application is subject to the standard regulatory timeframe of 40 working days +/- public notification. As above, we are in discussions with APVMA and intend to address this as part of the revised registration by reference agreement.

Residues

Are residue trials based on VICH guidelines accepted?
The ACVM Residue Information Requirement document is based on the VICH guidelines as much as possible. Registrants need to check whether there are any differences between the two before undertaking trial work, bearing in mind the ACVM Residue Information Requirements take precedence. We are reviewing our document, and will continue to use the appropriate VICH guidelines as much as possible.

What if the VICH requirements don't match the ACVM Residue Standard?
See the answer above.

Agricultural Chemical Session

Efficacy Working Group

What is happening with the working group?
We are considering whether the document drafted needs to be underpinned with a base efficacy standard to provide the context for the information in the document. Currently, this work has been assigned a lower work priority but still is on the ACVM work plan.

PSA claims

What are the requirements to support upgrading a limited claim to a full label claim?
It is noted that researchers are able to do more field trials (as opposed to laboratory or vine pot trials). This will assist registrants to supply efficacy data based on proper field trials, which should provide more meaningful results. Currently, such requests are being treated on a case by case basis. As industry has a significant interest on products making PSA claims, we will notify both Zespri and KVH of all applications involving PSA claims.

Sheep leaf plucking

What will be the requirements going forward in this area?
We will be working with industry and registrants on determining information requirements going forward. In the short term, a default withholding period may be practical for most agricultural chemicals.

Expiry specifications for products

ACVM was asked to review these. What progress has been made?
This is on the ACVM work plan and some initial work was undertaken based on the document provided by Agcarm. However, this work has been pushed back due to lack of resourcing and high workload of applications we have received recently. We will look to pick this up again, subject to resourcing. As part of this, advice on what specifications manufacturers use in this area would be welcome.

Are the release and expiry specifications still part of the required information on the PDS (Ag chems)?
Yes.

Biological pesticides standard

When will the biological pesticide information requirements be released?
This is on the work programme, but is lower in priority than other items.

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