ACVM

Ministry for Primary Industries
Manatū Ahu Matua

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Annual fees: reminder to registrants

Earlier this month, product registrants received a letter explaining the annual fee process. Your participation in the process is crucial. We need you to:

- check your products on the product list posted to you, and
- advise us of any products you wish to have de-registered by **17 June 2013**.

Please note that you do not need to return the list to us if there are no changes to your product list. Contact us for further information (approvals@mpi.govt.nz).

Revised trade name naming convention labelling requirements

In response to concerns about the trade name product naming convention requirements in our labelling information requirements documents for veterinary medicines, agricultural chemicals and vertebrate toxic agents, we consulted with Agcarm and ARPPA on revision of these sections.

We agreed to revise requirements to align the wording as much as possible with the equivalent sections in the APVMA labelling guideline documents in Australia. This will help facilitate harmonised labels between the two countries.

We also agreed that the revisions would not be backdated, so any existing trade names will not require amendment.

In addition, the new requirements will not be enforced until **31 December 2013**. Hopefully, this will minimise any impacts for registrants who are currently working on branding products for registration applications to be made in the next 6 months. (If any registrant believes this timeline is not suitable for an application, contact us for advice--email address above.)

The labelling requirement documents are being updated with the revisions and MPI branding. They will be on our website in the next month.

Rebranding and revising documents

While rebranding all our documents with MPI information, we are reviewing content and making any simple changes needed. Any documents that require significant changes, such as the *Chemistry Information Requirements for Veterinary Medicines*, will be rebranded now and the content will go through the usual consultation with stakeholders at a later date.

As advised during the recent workshops, we are also revising the PDS forms used for registration. The new forms will be used for product information and the application/payment details will be separate (see 'cover letter' and 'PDS' in the article on the application process below).

Successful prosecution after MPI investigation

Castration of horses is a major surgical procedure that only a veterinarian can perform legally. If done incorrectly, it can cause severe or fatal repercussions.

A man who promised last year to stop illegal horse castrations has been convicted and fined after being caught doing it again. Gisborne farrier John Sheridan had been performing castrations on the East Coast for about 50 years. He used chloroform as an anaesthetic, which is illegal. When he was caught in an MPI investigation last year, he said he had carried out hundreds of castrations and wondered when he would get caught.

Sheridan was advised his actions were illegal. He agreed to stop and handed over his supply of chloroform. He and three station owners were given formal warnings, advising them that, if they were caught again, they would be prosecuted.

He received the warning on June 12. Two weeks later, on June 25, investigators found a horse that had been castrated within the previous eight days. The horse's owner told investigators he had paid Sheridan $200 for the procedure.

Sheridan admitted performing the castration. He said he had turned down about 100 requests since May and that castrations generated about $50,000 a year for his business.

He pleaded guilty to a charge of performing a surgical procedure in contravention of the Animal Welfare Act and of knowingly using chloroform in contravention of the Act. Sheridan appeared in the Wairoa District Court in March 2013 and was fined $750 on each charge. He was also ordered to pay court costs of $132.89.

National and international meetings

Minor crop workshop

29 April 2013, Wellington

MPI along with the Ministry of Business, Innovation and Employment (MBIE) and the NZ Environmental Protection Authority (EPA) attended a workshop on minor crops hosted by the Vegetable Industry Agrichemical Strategy Working Group. The meeting was held to discuss barriers to obtaining label claims (or registrations) for minor crops in New Zealand.

The workshop assisted all participants to gain a better understanding of the issues from each different industry's/regulator's perspective. As well as considering the problems, some ideas on solutions were discussed. These included the possibility of having a co-ordinator role to facilitate new registrations and additional label claims for existing registrations for minor crops.

Organisation for Economic Co-operation and Development (OECD) Working Group on Pesticides

15-19 April 2013, Paris

Warren Hughes attended the April OECD Working Group on Pesticides (WGP) meeting along with Government Only and Global Joint Review meetings.

Key items of interest were:

- New Zealand's proposal to develop a product chemistry guidance document was accepted.
- The vision of the WGP was discussed.
- An update of the work of the Economists' Working Group (EWG) on pollinators and pesticides was presented.
- Terms of reference for the OECD Network on Illegal Trade of Pesticides EWG were approved.

There was also positive feedback from OECD members on New Zealand's hosting of the OECD Registration Steering Group and Risk Reduction Steering Group meetings held in Queenstown in November 2012.

Codex Committee on Pesticides Residues (CCPR)

6-11 May 2013, Beijing

Warren Hughes and Dave Lunn from MPI, and two industry representatives attended the recent CCPR meeting. From New Zealand's perspective the meeting was successful. The vast majority of proposed Codex MRLs have progressed, good progress has been made on updating the risk analysis principles of the Committee, and adoption of Codex MRLs for sulfoxaflor as part of a pilot project is moving forward. In addition, New Zealand is supporting one compound that has been placed on the priority list for evaluation commencing in 2016.

The meeting also discussed the issue of resourcing and financing the work of the Joint FAO/WHO Meeting on Pesticides Residues (JMPR) who undertake the risk assessment of toxicological and residue data on behalf of the Committee. There are no simple solutions to this on-going issue, which can lead to delays in assessing compounds.

Workshop highlights

We have been asked to provide a summary of information presented at the 2013 ACVM workshops. There is too much to cover in one issue of News and Views, *so we will present 2 or 3 topics each time. This issue covers data protection and the application process.*

Data protection update

During the 2013 ACVM workshops, data protection under the ACVM Act was a topic of great interest. Here is a summary of the information presented and the following Q+A sessions.

FYI:
Confidential Supporting Information (CSI), also known as 'data protection', relates to trade secrets and commercial information.

I**nnovative active ingredient** means not received before in an application for registration of a Trade Name Product except by the applicant for a provisional registration.

Current rules of data protection

Protection periods

- When an application for provisional registration is received, CSI is granted protection for 5 years.
- Once registered (or declined registration) CSI has 5 more years of protection, but registration has to be within 5 years of the application to get this additional 5 years.
- Once the protection period expires there is no ability to extend the protection period for new uses etc.

CSI protection period obligations

- MPI cannot use CSI to support another application and must keep CSI confidential, but MPI can use the CSI to support another application if the CSI owner agrees.
- CSI can be disclosed for public health reasons to other government departments for appropriate purposes, to international bodies provided MPI is satisfied they will keep CSI confidential.

HSNO Act

- The HSNO Act has no specific provisions for data protection for part 5 approvals, but does reference data protection under the HSNO Act.
- Where the application for registration is made under the ACVM Act for an innovative active ingredient prior to or at the same time as a part 5 application is made under the HSNO Act, EPA will protect CSI with this application for the same period under the ACVM Act.

Proposed rules

Innovative active ingredients

An extra year of protection will be granted for each additional use with a maximum of 3 extra years (a total 8 years), but applications for these additional uses must be made within 3 years of the first registration.

Existing registrations

CSI will support new uses and significant reformulations.

Proposed amendments

CSI will no longer be restricted to the original applicant for provisional registration.

Process and timeline

- MPI is currently finalising the policy details for the proposed legislation changes and is in the process of finalising drafting instructions for the Parliamentary Counsel Office.
- Amending the Act is a parliamentary process so the timeline for passing the legislation is dependent on the Government's legislative timetable and other factors. MPI is working on the basis that the legislation will be passed in 2014, but we cannot guarantee this.

Workshop questions on CSI/data protection	**Answers** **Note: if a question required consultation with MPI Policy, their input has been included in these proposals**
What information will be kept confidential? For example, for an insecticide adding a minor crop?	The same information that would be kept confidential under the existing rules, for example CSI.
Please provide clarity on provisional registration data protection.	Any CSI submitted with an application for a provisional registration for an innovative active ingredient would be protected for 5 years. In general, most provisional registration applications contain CSI. The changes to the data protection rules around provisionals are related to who can apply for protection: previously if company A held a provisional registration of an innovative active, company B could not get data protection if they were the first to fully register the innovative active. Under the new rules, company B can get data protection in this situation.
Are generic formulations covered by data protection if new data is generated?	Currently, no. However, under the future data protection rules significant reformulations (such as two generic active ingredients formulated together for the first time) will gain some data protection.
Will data protection extensions apply retrospectively? For example, for products already registered but the registrant wants to apply for a new use?	New uses for existing registrations and significant reformulations already approved under the ACVM Act will not gain data protection retrospectively.
Can I apply for new uses now and hold off registering the new use and get data protection for it when the amendment is made to the ACVM Act?	MPI is considering this matter in finalising the drafting instructions for the amendment. MPI will clarify this matter once the first draft of the amendment is finalised.
Will there be consultation with industry before the final draft goes to the select committee?	MPI intends to consult with industry on the proposed amendment to the ACVM Act.

The application process

'The application process' was a critical presentation of the workshops. Submitting a 'good' application means more predictable outcomes, quicker appraisal times, and less regulatory costs.

Common reasons for declining applications

Applications are declined for a variety of reasons. The most common are:

- Minimum information is not provided.
- Forms are not fully completed.
- Non-conformances raised by the data assessor have not been addressed.
- Insufficient or non-technical arguments are provided.
- There has been a consultant/data assessor conflict of interest.
- Data assessment provided is inadequate.

Essential documents

Cover letter (to be replaced by application form)

For several years we have been explaining what is needed in a cover letter. HOWEVER, we still receive many applications without the minimum information. During the recent workshops it was clear that many applicants are uncertain about cover letters.

For this reason we are developing a new short application form (to accompany the PDS) that will replace the cover letter. The form provides fill-in and tick boxes for the information we need. The form should make applications easier for you and for us. (The form will be ready to use with the MPI rebranded version of the PDS –see article on rebranding above.)

Label

- The label must comply with ACVM labelling requirements, which are available on the website.
- Two copies of the final marketed label are required, but if you are sending labels electronically, hard copies are not needed.
- Word document copies are acceptable until marketed labels become available. **Then the marketed label must be submitted.**
- If the marketed label needs to be updated or changed, supply the new version of the marketed label. If you are making label changes, it is helpful to include one version with the changes tracked and highlighted.
- The label on the public register is the approved label so:
  - In the case of a new product, a marketed label should be provided for the register before the product is put on the market. A text doc is acceptable as a temporary measure only.
  - In the case of an existing product submitting for label updates, what is on the market may temporarily differ from that on the register until current label supply is depleted.
- When renewing your registration, YOU MUST PROVIDE LABELS.

PDS

- The PDS is to be sent electronically but must include an electronic signature (in PDF format). If you are unable to send an electronic version, send a hard copy.

- All applications must be in the current PDS format -- this is not negotiable. The MPI rebranded PDS and the short application form that replaces the cover letter, which will be available soon, should be used for all new registration applications from **1 September 2013.**
- 'Responsible manufacturer' has been deleted from the PDS but manufacturing specs (including manufacturing sites) are required.

Presentation

- Send electronic submissions if possible.
- Clearly identify each document.
- Invoicing
  - Advise who should receive invoice to if it is someone other than registrant, i.e. consultant/agent
  - Include Purchase Orders with your application.
- Include all relevant information.
- Be familiar with standards.
- Get GOOD advice.
- Make use of resources available.
- Complete previous applications before you make another application.
- Do not drip feed documents.
- Do not ring-bind PDS, DAS reports, labels.
- Do not present each page in plastic sleeves.

Data assessment reports

- Read carefully.
- Address data gaps identified.
- Do not ignore deficiencies.
- Do not rely on assessor recommendations.

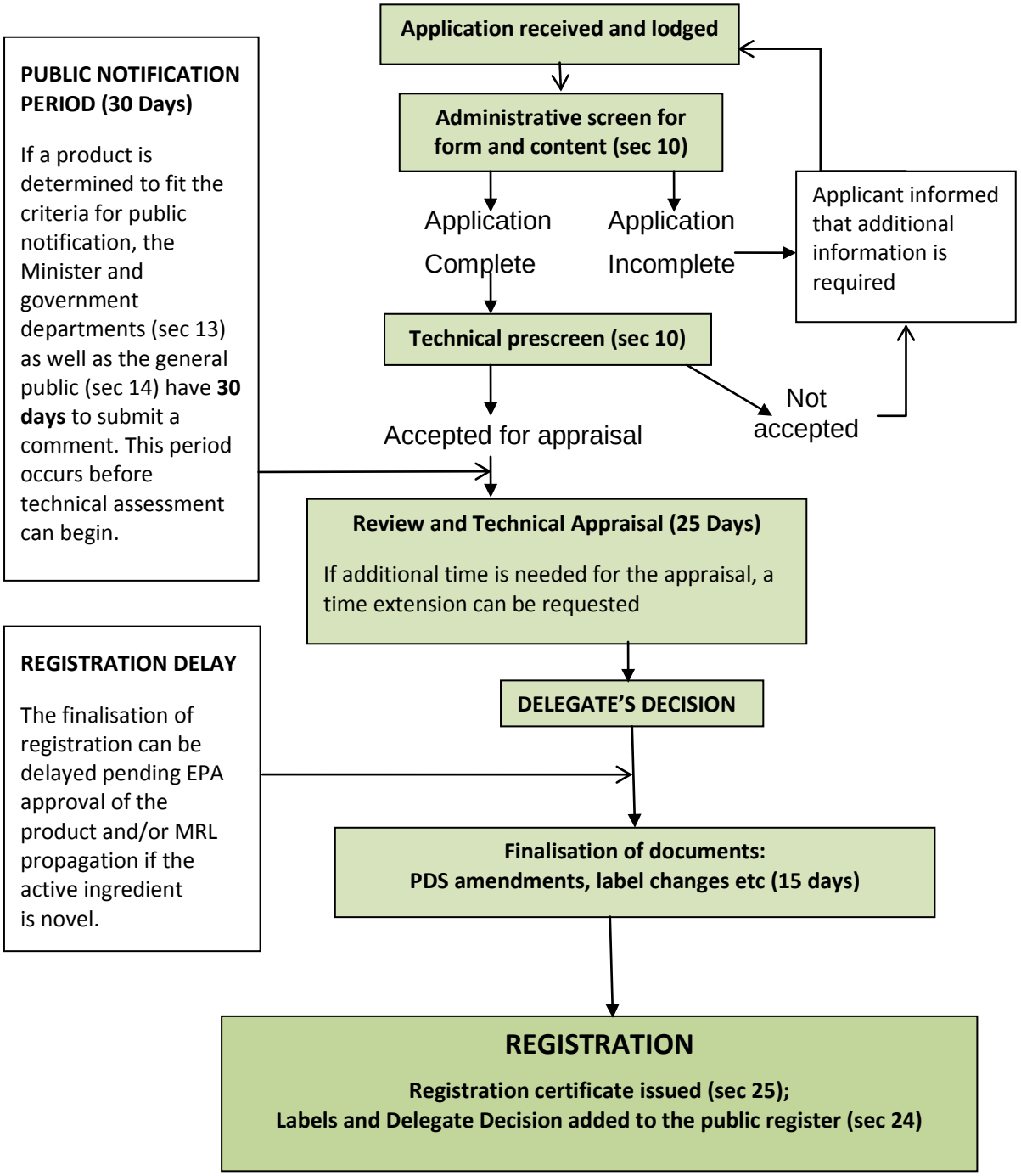
Deviation

- Very simple deviations may be addressed with the application.
- Deviation requests may be appraised in the regulatory review.
- Deviation requests may be appraised prior to accepting the application but will ONLY be advice--NOT a formal approval.
- Deviation requests must be included in the application for registration and will be considered in the appraisal at that time
- Data supporting a deviation must be data assessed prior to submission.

EPA requirements

- For formulation changes, provide evidence that the new formulation is still covered by an EPA approval (for example, SOS response letter)
- If you are making changes to parameters such as application rates, check that you are not breaching the conditions of your EPA approval
- An ACVM registration cannot be issued until we have evidence of an EPA approval.

Application Process Flowchart



Workshop questions on registration applications	**Answers** **Note: if a question required consultation with MPI advisers, their input has been included in these answers**
What is the average application queue length?	This changes week to week. We have recently introduced a group rather than a personal queue system. All agricultural chemical and VTA applications are placed in one queue and all veterinary medicines applications are placed in another queue. Assessors draw from these queues, which means that all applications are dealt with in order of receipt and individual assessor absence from the office has less impact on the order of processing.
How many ACVM assessors are there?	Currently we have three veterinary assessors, four ag chem assessors, and one who does work on both sides.
Can registrants be consulted before a 'not accept' at prescreen?	'Not accept' is determined case by case, and the email sent out after a not accept is the best way to address that.
How do you determine when to submit a deviation, i.e. before a registration application or with it?	This depends on how involved the deviation is. If it is a full efficacy, safety, and/or residues deviation for a very simple product, or if it is a partial deviation covering a particular aspect of the data not covered (such as one species of worm when others are present in trial work), the deviation can be assessed with the application. If it is complicated or involved, the deviation is done first to ensure that the registration application assessment does not exceed the regulatory timeframe.
Why would you need to sign an incomplete PDS? Why bother signing it on submission (or rejecting it because it's not signed) if we know it will need amendment later?	Signing it at submission of the application states that the PDS is accurate and complete as it can be at that point. The process and the PDS content are currently under review.
With respect to re-registration, why can't you always be assured the previous registration number?	Re-registration is a new application, and all new applications are assigned new registration numbers. Retention of the previous number can be requested but cannot be guaranteed.
Can ACVM consider including registration expiry dates on the register?	We will consider it. It may improve registration renewal compliance.
If a product expires, does it always have to be re-registered?	If there is an open application, then no. We will acknowledge the product is progressing a variation of some kind and will update the registration status at

	the end. If the product simply lapses with no contact with the ACVM to discuss the delayed renewal, yes.
How long is data held after product expiry or cancellation? Can the data be cross-referenced even if the product is no longer on the market?	Data belongs to the registrant and is only held by MPI. Once the product is no longer registered, the data is no longer available for cross reference unless there is a short time delay for reinstatement of the same product and/or there was an error made in cancelling it. This will be decided on a case by case basis.
Regarding electronic submission of data – why not harmonise with the APVMA for format?	Electronic format guidelines used by overseas regulators were reviewed when developing our system requirements. However, their system requirements are quite different to those here and would not meet our requirements. If a package is sufficiently easy to navigate and contains all the pertinent information, there shouldn't be any reason why you couldn't submit the APVMA **data package** to us (obviously forms will differ).
Does the ops team actually notify applicants of the products going to public notification?	They should be notifying at the time of submission to the *Gazette* for public notification. Will be followed up to make sure they are.
Can public notification be done under a code name like with the EPA? Public notification may present a commercial disadvantage as product details are released.	Public notification under the ACVM Act is related to registration, which is always product specific. The notification must specifically identify the product, and part of that identification is the trade name. Only the product name, active ingredient, and proposed claims are publicly notified – no data, chemistry, or manufacturing information is made public. EPA notification under the HSNO Act is substance specific, so a code name is possible.
Are registrations not withheld from the registry on request anymore?	Registrations are required by the Act to be placed on the registry immediately after registration is finalised. Only the labels have ever been withheld for the registry at request, but this practice for non-regulatory (i.e. commercial) reasons contravenes one of the purposes of the ACVM Act. The information must be available to consumers and border clearance officials. We are considering possible alternatives.
Could a programme be implemented where the label is uploaded at the time of registration but is not visible publicly for up to 6 months? Could just be a bit of programming from MPI IT?	Same as previous answer.
This is not consistent with experience -	This should not be possible unless there was an error

there have been incidents where a product has previously not been on the register before but suddenly appears with an older registration number [the example mentioned was 2002].	in database entry because registrations are updated nightly, and registrations must always be put on the register immediately after registration. If you have seen this occur, please let us know so we can follow it up.
The EPA now requires draft labels at assessment. This may impact either ACVM or EPA approval if the final label is significantly different (for example, final approved dose/application rates or species/crops are different from draft).	We will discuss this with EPA at the next joint meeting. EPA may be using the draft labels to get use rates for their modelling.
If a product is trialled (provisional registration) but is not efficacious, does the fact that it's not efficacious need to be notified to ACVM?	No, only trial site notification is required.
Do products have to present all data held on a product at registration? Or can data putting the product in a negative light be omitted?	We prefer you to present all data, but there is no way to enforce this if we are not aware other data exists.
Can anyone be a data assessor?	Data assessors must be experts in the fields for which they are assessing data, and demonstrate an understanding of our standards. CVs must be provided for any new data assessors, and we do have the option of rejecting an assessment or requiring peer review if we consider it is deficient.
How do we know who is a good data assessor?	Right now, use networking as we cannot recommend any specific assessor over another. We are looking into recognising data assessors as a way of managing the quality of data assessments, but in the meantime we urge all registrants to check their data assessments for completeness and quality before submitting a registration application.

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