

News and Views

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Workloads and timeframes

The ACVM Group is experiencing high volumes of applications with limited resourcing this month. In addition to this, the pressures on MPI in responding to the current dairy trade issues mean that some of our normal timeframes may not be met. We are doing our best and apologise in advance if this impacts any of your applications or query response times.

Animal Feeds Review

Background

Substances composed of nutrients and intended to provide a nutritional benefit that are fed to animals are considered oral nutritional compounds (ONCs). An agricultural compound that is a therapeutic or pharmacological substance or preparation may be incorporated into an ONC if:

- the agricultural compounds are registered under the ACVM Act and
- the incorporation of the agricultural compounds is consistent with any conditions of their registration:
 - the registered product approved efficacy claims, species and class of species (such as young, lactating) and dose rates for use will be claimed on the ONC
 - all required regulatory (accurate product identification, registration number, conditions, withholding period etc) and warning (contraindications etc) statements from the registered product will be included on the label
 - the ONC will be of a product type (e.g. supplement, milk replacer, completed feed) approved as a recipient for the registered product.

A number of feed mills and third party manufacturers of ONCs are not complying with these requirements and some products are not 'fit for purpose'.

Review

MPI is reviewing the regulatory framework surrounding animal feeds, which are regulated in New Zealand under the Biosecurity, Agricultural Compounds and Veterinary Medicines, and Animal Products Acts. The review aims to examine the existing animal feeds sector systems and develop a consistent 'all hazards' approach that identifies and manages risks across the sector.

As part of the review, MPI asked stakeholders for their views on the existing animal feeds system in an online survey. The results from the survey:

- indicate that clarification surrounding legal requirements is needed, and
- highlight a desire for increased activity in the areas of importation, compliance and adequate product labelling.

The survey results have been used to help identify areas or issues that need addressing and to prioritise work streams for the next (fourth) stage of the review. MPI is talking to a number of stakeholder groups and organisations including the NZ Petfood Manufacturers, NZ Renderers and NZ Feed Manufacturers Associations.

The fourth stage of the review will include analysis of current regulatory requirements, standards and policies, and assessment of the suitability of existing controls. The level of understanding of the current controls as evidenced by compliance activity and industry feedback will be considered. It is anticipated that current controls will be confirmed as adequate or revised (if necessary) and communicated to industry at the completion of the review.

For an overview of the review, read *Animal Feeds Review On-Line Survey* (<http://www.foodsafety.govt.nz/industry/sectors/animal-feeds/review-survey.htm>).

Use of 'batch analysis' condition of registration

One condition of registration that may be applied to an ACVM product relates to provision of a batch analysis from a manufacturer after approval. Condition 86 states:

"The registrant must provide a batch analysis, which confirms that the product meets the approved release specifications, from the first production batch at the new manufacturing site to MPI for approval prior to sale of product from this new site."

This condition is applied if a batch analysis from a commercial batch has not been supplied from the formulation manufacturer. However, currently many registrants are requesting this condition for 'just in case' manufacturers. This is not the intended purpose of this condition, nor will it be used in this way in the future.

Condition 86 will be applied at the ACVM Group's discretion, mainly in the following situations:

- the proposed manufacturer will not manufacture the product until ACVM has granted registration of the product
- the proposed manufacturer will manufacture 'in the very near future' (meaning months, not years).

Reduced registration period

The addition of condition 86 in most cases will mean the product has a reduced registration period of **one year**. The product will continue to be registered in one year cycles until a batch analysis is provided and condition 86 can be removed from the registration. Removal of the condition will require approval of a batch analysis from the manufacturer demonstrating that a production batch of

product conforms to specifications. The approval of any condition 86 batch analysis will be charged on a cost vs time basis.

Adding new formulation manufacturers

The Smart Track process is the appropriate way to add new formulation manufacturers for an already registered product. A batch analysis, or an acceptable reason why one has not been provided, must be supplied each time.

Depending on product type, additional information requirements must be met for Smart Track applications. However, these are not related to condition 86 so they are not covered in this article.

Customer satisfaction survey

Recently we emailed a survey examining customer satisfaction in the areas of service and communication, the application process, and the website to 'key account' ACVM registrants. They were asked to complete the short multiple choice survey and to add comments. Here is a summary of questions and responses.

Service and communication

Q: Do operations staff members respond quickly when you request information by phone or email?

Q: Do we resolve your issues in a satisfactory and timely manner?

Q: If you raise issues with us, do you feel your comments/ideas are considered seriously?

These questions had four possible responses: ALWAYS, USUALLY, SOMETIMES, NEVER. We did not provide a central position to prevent 'fence sitting'. Responses were mostly on the + side of the continuum, ranging from 74% to 83% positive.

Q: Do you read our online newsletter, ACVM News and Views?

Most respondents (91%) read *News and Views* at least occasionally and 50% always read it.

Q: What is your preferred method of communication?

We gave the option to pick more than one answer. No surprise that 100% chose email, followed by phone (32%) and workshop (24%).

There were not many comments for this section and no 'themes' that would indicate a significant problem. A few respondents mentioned that it took longer for renewals or for replies to emails than expected, but others commented on rapid response times and helpful staff.

Application process

Q: Do you find our standards/instructions and application forms easy to understand and complete?

Respondents were given a YES/NO choice for this question and 79% ticked YES.

Q: At what stages in the application process do you want an acknowledgement?

Respondents want an acknowledgement when their application is received and several indicated that they want one when it completes pre-screen.

Q: Can you submit electronic applications?

All but two respondents said they can submit electronic applications. One did not reply to the question and one said NO. (Perhaps the one who said NO misunderstood the question because the survey was submitted electronically.)

Q: What word processing software and version do you use?

Word 2007 or 2010 is used by at least 80% of respondents—a few just said Word.

Respondents were asked to choose between two sample application form styles—one with shaded question boxes and one with no shading. (This question was asked because shading makes files

considerably larger.) All respondents indicated that they prefer application forms with shaded question boxes.

Comments indicated that registrants want more communication about their applications. Some people requested more examples in the guidelines to help complete forms. Several suggestions about application forms (e.g. larger font size, no 'protection' so it is easier to cut and paste) were made and are being implemented. (See article below on rebranded forms.)

Website questions

Q: Is the website information on requirements for approvals easy to find and understand?

This question had four possible responses: ALWAYS, USUALLY, SOMETIMES, NEVER. The majority of respondents (94%) replied USUALLY or SOMETIMES.

Q: What type of information do you access most frequently?

The most frequently accessed information on the website is the Public Register, followed by application forms.

Comments on the website are mixed. Some respondents said they have no problems with it but several mentioned the 'down' time, slow response, issues with the Register, inadequate search functions.... A few comments showed that people need more information about the website contents. For example, one person asked for FAQs and another asked to have agricultural chemical forms separate from veterinary medicine ones—both of these requests already exist. (See article below on navigating the website.)

One person mentioned downloading a document that was not the latest version. This should never happen—our procedure calls for old versions to be removed when a new version is uploaded. Please let us know if you come across this situation.

Overall

Q: Overall, are you satisfied with our service?

Most respondents (91%) are satisfied with the overall service.

Suggestions for improvement focused on various aspects of communication, consistency, more user-friendly application forms and faster turnaround times.

We thank those (57%) who took the time to reply to our survey. We are already implementing many of the suggestions.

Navigating the website

Responses to the ACVM survey (see above) indicated that more information about using our website would be useful. Here are a few navigation tips.

Relevant documents

If you just want to see documents/forms relating to your product type, say ag chems, click on Agricultural chemicals on the ACVM home page. On the Agricultural chemicals page, you will see a left hand menu that includes Documents. Clicking that will take you to documents and forms that apply only to ag chems.

Quick links

The most frequently accessed areas of our website, the Public Register and application forms, have Quick Links on the right hand side of the ACVM homepage.

FAQs

On the ACVM homepage, click on About ACVM. This will take you to a page that explains ACVM regulation in New Zealand and has FAQs. (If you have suggestions for other FAQs, let us know.)

Restricting e-Library search

When you search for a document in the eLibrary, which can be accessed from the top menu of every page, you can limit the number of choices that come up.

- Type in the name of the document or key words.
- In the line below, pick a publication type rather than leaving it on the default All. Forms & templates or Manuals & guidelines cover most ACVM documents. To search for an audit summary, click Reports & strategy. To find *News and Views*, click Newsletters & circulars.
- Then click search.

Rebranded forms

As advised several months ago, we have rebranded our application forms. We delayed rebranding the PDS forms to implement some changes in requirements and intended to have them in place this month. However, we are adding suggestions from the recent customer survey (see above) to the rebranded PDS forms. This has delayed implementation slightly, but the new forms should be more user-friendly. The draft forms are going to industry groups for comment and will be available soon.

Workshop highlights

We presented some topics from the 2013 ACVM workshops in the May issue. In this issue we cover other topics that we are asked about frequently: class determination and research authorisation.

Class determination

What is ‘class determination’?

Class determination is a process* used by the ACVM Group to:

- determine if a product is an agricultural compound (veterinary medicine/agricultural chemical/vertebrate toxic agent/fertiliser/oral nutritional compound) under the ACVM Act, and
- if the product is an agricultural compound, determine whether it is exempt from registration.

*Note this process is based on information supplied by the applicant. Incorrect or changed information can impact the class determination.

How does ‘class determination’ work?

Step 1: ACVM Group determines if the product meets the ACVM Act definition of an agricultural compound

- If no, the product is not regulated under the ACVM Act. End of story.
- If yes, the product is an agricultural compound and requires authorisation under the ACVM Act. Go to step 2.

Step 2: ACVM Group determines if the agricultural compound fits one or more of the exemptions listed in the ACVM (Exemptions and Prohibited Substances) Regulations 2011

- If no, another form of authorisation under the ACVM Act is required. Usually the authorisation is by registration (section 21), but sometimes provisional registration (section 29) or approval in special circumstances (section 8C) is appropriate.
- If yes, the product is exempt from registration under the ACVM Act. Go to step 3.

Step 3: ACVM Group provides official confirmation of exemption status

The applicant is given a class determination letter, which is valid for three years, to present to Border Inspectors for import clearance of their agricultural compound.

How long does class determination take?

The process can take up to 15 working days.

Are there ACVM obligations for products exempt from registration?

If your product is exempt from registration, you must make sure you don't invalidate the exemption by non-compliance with conditions of the exemption (Regulations 7 to 13 of the ACVM Regulations) when you import, manufacture, sell or use the product in New Zealand. Basically, you must be sure that your product:

- is fit for its intended purpose
- conforms to specifications, and
- is represented truthfully and accurately.

Is a class determination legally required?

Getting the ACVM Group to make a class determination is not a legal requirement. You can make your own 'determination' about your product, but if your decision is wrong, you could end up breaking the law.

For **commercial** imports of exempt products, however, you do need a class determination letter to present to border officials before products will be released. This is a procedural rather than a legal requirement.

Research authorisation

ACVM authorisation is required before a substance can be imported, manufactured, sold or used as an agricultural compound in New Zealand. Research corresponds to a 'use' situation.

ACVM authorisation for research is required even when:

- registration of the investigational product is not the primary objective
- produce from the treated plant/animal is excluded from food/feed chain.

ACVM Act tools for research authorisation

Three ACVM Act tools can be used for authorising research:

- provisional registration
- special circumstances approval for research (formerly 'research approval')
- regulatory exemption via operating plan.

Tool	Provisional registration	Special circumstances approval for research	Regulatory exemption via operating plan
ACVM legislation reference	Section 27 ACVM Act	Section 8C ACVM Act	Entry 3, Schedule 2 ACVM Regulations
When used	<p>This tool is used only when the investigational substance is a 'trade name product' (TNP):</p> <ul style="list-style-type: none"> • it has a trade name • it has a fixed formulation • it is packaged or has packaging specifications. 	<p>This tool applies to the majority of research authorisation applications.</p> <p>It is appropriate when the investigational substance does not have the characteristics of a TNP, but it can also apply to products that meet the TNP characteristics.</p> <p>It is used even if registration is not the objective of the research.</p>	<p>This tool applies for research, testing or training activities. The exemption is person/organisation specific.</p> <p>The person/organisation must have an operating plan approved under section 28 of the Act.</p>
Data protection provisions of ACVM Act apply?	YES, if the investigational substance contains an <i>innovative</i> active ingredient	NO	NO
ACVM conditions imposed?	YES, as specified in the provisional registration	YES, as specified in the special circumstances approval	YES, as specified in the ACVM Regulations
Associated regulatory approvals (HSNO approval, Biosecurity clearance) required?	YES	YES	YES

When ACVM authorisation is not required

Research using substances that are not agricultural compounds

- If the investigational substance does not meet the statutory definition of an agricultural compound, ACVM authorisation does not apply. Examples:
 - research on human medicines or human cosmetics using animals as experimental models
 - research involving administration of substances to animals for studying basic physiological parameters in the species
 - research on fungicides to test efficacy in protecting wooden buildings from rot.

Certain research using substances that are agricultural compounds

- Research using trade name products registered under s21. Examples:
 - residue trials on goats for a registered anthelmintic trade name product with sheep as the label-approved species (with no restriction for use on other species)
 - efficacy trials for a registered herbicide on plant species not listed on the label when that product has no restrictions for off-label use
- Research using agricultural compounds exempt from registration. Examples:
 - copra meal fed to animals for nutrition research
 - fertiliser applied to plants to study crop yields.

Research authorisation is not necessary if the investigational product is not intended to be administered to plants or animals (such as for stability trials or laboratory analysis work).

Staff update

Earlier this month we said farewell to **Beth Dye** (Senior Adviser Chemistry). Beth came to us from the EPA (then ERMA) five years ago. Her ERMA background and expertise in chemistry were welcome additions to the ACVM Group. She was a valuable member of the team -- always willing to share her knowledge. We will miss her and wish her all the best.

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