



AgVetLink

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SPECIAL ISSUE FOR REGISTRANTS

Update Now!!!

The Agricultural Compounds and Veterinary Medicines (Transitional Provisions) Regulations 2002 provided that all products covered by the registration provision of the ACVM Act need to be updated before 1 July 2004.

To date there have been relatively few requests for updates – less than 20%. This means that the ACVM Group is expecting to deal with a rush of applications in the first six months of 2004, and a potentially high level of compliance activity following 1 July 2004 for registrants who have not actioned the updates.

We have recently held workshops to work with ERMA New Zealand and with both veterinary medicine and plant compound registrants. The workshops helped us to identify some of the registrants' concerns that have meant delaying their update applications. The workshop participants also thought it would be useful to clarify areas where there might be misunderstandings about what is required and to let registrants know what would happen to products where the registrant fails to meet the deadline.

I would encourage all registrants to read this edition of *AgVetLink* very carefully because there are significant cost

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savings for updates made on time, and the costs and inconvenience of non-compliance are likely to be considerable. If you have any queries about the update process, please contact Maree Zinzley, Programme Manager, ACVM Operations (04 463 2564 or email maree.zinzley@nzfsa.govt.nz), or your Advisor in the Operations team.

Debbie Morris, Director, ACVM Group

AgVetLink is provided free of charge. To be added to the mailing list, send your contact details to Gill Wilson (address below). AgVetLink is also available on the ACVM website (www.nzfsa.govt.nz/acvm).

AgVetLink is produced at least six times annually by the New Zealand Food Safety Authority's Agricultural Compounds and Veterinary Medicines Group. The newsletter is of special relevance to those interested or involved in all aspects of agricultural compounds and veterinary medicines. It contains regular updates on implementation of legislation, notifications, new standards and policies, consultation, international agreements, and other information.

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Disclaimer: This publication is intended only as a guide. It is not a legal interpretation of the legislation discussed.

Questions and concerns about updating

What is the deadline?

All registered products must be updated to ACVM Act conditions by 1 July 2004.

What information is needed for an update application?

- a covering letter
- a Registration and Product Datasheet
- three copies of the **revised draft label** content.

There is more detail on the information required on page 3.

What does an application to update cost?

A simple update is done at no charge providing that it is received prior to 1 July 2004. Applications after that date will be charged on the basis of the time taken. Where the update shows a need for a variation of the registered product, normal costs will be incurred for the type of application.

What are the common concerns from registrants and how are they being addressed?

HSNO Act label requirements for the products have not been finalised yet.

The update is for ACVM Act requirements only at this stage. Registrants need to put in an ACVM application prior to 1 July 2004, but there is no need to finalise labels for a period of up to two years. Products with old labels will be able to remain in the market place in most cases.

In the interim ERMA New Zealand has advised that proposed changes to the HSNO Act mean that it is unlikely that there will be tracking requirements for Class 9 substances, and that it is also unlikely that it will be a requirement to show EELs or TELs on the label.

Agcarm has developed a labelling guide for registrants to translate the HSNO and ACVM Act requirements into label statements for registrants. This guide

is available free of charge on their website (www.agcarm.co.nz) or via a link from the labelling parts of the ACVM website.

We don't know if the product will attract 'approved handler' status under the HSNO Act.

ERMA New Zealand has advised that they expect this to be clarified early in 2004.

It is expensive to get label proofs or final labels for the ACVM Group updates.

The ACVM Group does not require final labels. Updates will be approved on the basis of proposed label content or draft labels for ACVM Act purposes only. Once HSNO requirements are finalised and final labels are confirmed, the ACVM Group will update the information held on the website free of charge. Charges for making label changes will be incurred only where there is also a change to the registration or registration conditions of the product.

What happens to stock-in-trade for products with old labels?

The ACVM Group works on the basic premise that in the vast majority of cases, the best way for 'old label' product to be disposed of is for it to be worked through the system and used as originally intended. For products in the control of the registrant, there will be a period of up to two years for product labels to be updated. ERMA New Zealand is considering adopting a similar policy (refer to the article on labels on page 3).

What will happen with products that are not updated on time?

The ACVM Group has an increased interest in compliance under the ACVM Act, and any products not updated by 1 July 2004 will be in breach of the conditions of registration. This means that it will be illegal to import, manufacture, sell or use the products until they are compliant. We have

developed a compliance process for any non-compliant products that is outlined in detail on pages 4-5.

Update applications received prior to 1 July 2004 will be processed free of charge, whereas any received after 1 July 2004 will attract charges based on the time taken to process them. In addition, there will be prohibition notices and restrictions placed on non-compliant products to prevent importation manufacture, sale or use until they are registered.

How is the ACVM Group going to manage the flood of applications?

The ACVM Group has already taken on additional part-time staff to assist with update applications, and we have plans in place to take on more as the workload increases. As a general rule, products that come in early will be given the full three year registration. Products that come a little later will be given a shorter registration period from under one year to up to three years, depending on the time that they come into the system. This means that we will be able to process the applications quickly in the knowledge that they will be revisited within the three year timeframe.

Who is the ACVM Group talking to about the process?

In addition to providing this special edition *AgVetLink* for registrants, we plan to communicate with the key user groups (Federated Farmers, VegFed, veterinarians etc.) on the processes described in this issue of *AgVetLink*. This will mainly be through a range of articles in trade journals and the like.

Information on non-compliant products will be provided on the website so that users can easily ascertain if the products they are intending to use are legal.

We will also advise various parties of their responsibilities under the ACVM Act, and the ramifications for users in relation to non-compliant products.

Labelling requirements for ACVM updates

It appears that some registrants may not have applied to update their products to ACVM registrations yet mainly because of confusion over labelling requirements. From the workshops run recently with ERMA New Zealand and industry representatives, it appears that the need for submission of final printed 'glossy' labels in order to update a product may have been a cause for concern, especially to those registrants who do not yet know of any labelling requirements under the HSNO Act.

We would therefore like to remind registrants that we only approve **label content** as it relates to risks under the ACVM Act.

Final printed labels are no longer required by the ACVM Group to finalise an application (but they are still welcomed when available).

The documentation required to update a product to an ACVM registration is:

- a covering letter requesting the update and confirming that no other changes are being made;
- a Registration and Product Datasheet (the latest version should be downloaded from our website);
- three copies of the **revised draft label** including all labelling components (where there is more than one pack size, all can be listed on one copy of the label unless the text varies for each size).

No fee is required for a simple update; however, any changes we identify from the current approval will mean a variation application and will incur the normal fees.

Where a product has more than one pack size, they will all be updated

simultaneously, though registrants need not update all sizes in the market place right away. If, however, there are changes to label content that are sufficiently important, we will require that all pack sizes in the market place be updated immediately. This will be worked through with applicants case by case.

We recommend that registrants note the labelling guide drafted by Agcarm that is currently available on their website (www.agcarm.co.nz). This guide translates both ACVM and HSNO requirements into useful label statements. We understand that it may be put to ERMA New Zealand and the ACVM Group for approval under the Acts at a future date. Further information is available in the November 2003 edition of the Agcarm newsletter.

ACVM updates: phase in requirements for stock-in-trade

The ACVM Group has been working with organisations (including ERMA New Zealand, Agcarm and ARPPA representatives, and other registrant companies) to minimise the cost to registrants and the time taken for updating registrations under the ACVM Act. Part of the process includes the consideration of stock-in-trade because under the ACVM Act a product cannot be imported, manufactured, sold or used if it does not comply with the conditions of its registration (or other approval). It is recognised that:

- registrants may have significant quantities of labels for a range of pack sizes on hand, and
- 'old' stock will be held by retailers and/or users.

ERMA New Zealand and the ACVM Group have been working with industry to minimise the impact in the area of

stock-in-trade. The ACVM Group has worked to the basic principle that, in most cases, the best way to deal with stocks of products with old labels is for it to be used as it was originally intended. The exception would be if the combination of old and new labels was contradictory to current legislation or cause for significant confusion.

Recognising this principle, both regulatory bodies are working towards a phase in period for getting updated labels on packs in the market place, rather than a 'drop dead' date for compliance. This takes into account the potential for long lead in times for relabelling (particularly where the labelling is done overseas) and the relatively high cost of changes. It is hoped that the phase in period should avoid most instances of having to relabel stock-in-trade. At this stage a period

of two years (from 1 July 2004) is being suggested.

Industry is providing advice to the ACVM Group and to ERMA New Zealand through Agcarm on what they consider an appropriate phrase in period. Rationale to support the period is also being collated. This advice will assist in setting ERMA requirements for a phrase in period. The ACVM Group intends, as much as possible, to use the same criteria. Hopefully this will fit in with the majority of industry needs. Registrants and/or retailers who fail to comply with this phase in period will be subject to ACVM Group compliance activity.

It is hoped to have guidelines in place for a phase in period by January 2004 at the latest. Information will be advised on the ACVM and ERMA websites.

Compliance process:

For registered products NOT updated to the ACVM Act by 1 July 2004

All registrants of animal remedies and pesticide products must update their products to the Agricultural Compounds and Veterinary Medicines Act 1997 by 1 July 2004 or the registrations will lapse.

This means that under the ACVM Act, **PRODUCTS WILL NOT BE ABLE TO BE IMPORTED, MANUFACTURED, SOLD OR USED.**

They must be updated in order to remain legally existing. Because the timeframe is set by Regulation, there is no opportunity for extension to the date of 1 July 2004 – registrants **must** have an application in the system.

Compliance process

This process covers the implications should a registrant not update their product(s) by the date of 1 July 2004. The ACVM Group will undertake the following procedure:

- Registrants will be advised in the near future of the products that they have registered that have yet to be updated. The ACVM Group will keep a running check on the progress of updates received into the system.
- An initial report will be run of all products to identify those that have not been updated by 1 July 2004, i.e. applications will be date stamped and must be accepted into the ACVM system by the end of business on 1 July 2004.
- Fees will be charged for any requests for updates received after 1 July 2004 on the 'time and materials' basis allowed for in the ACVM Fees Regulations.
- It is expected that prohibition notices (under section 65 of the ACVM Act) will be issued to importers and manufacturers for any products without an application for an update. These will remain in force until the product is approved as registered under the ACVM Act.
- The ACVM Group will maintain a list of products that have not been updated on the website.
- Where applications for updating have not been received by 1 August 2004, the prohibition notices will be extended to cover any stocks of product that have been sold to third parties that can be identified by searches of registrant records. The notice will prevent sale, but will allow return of stocks to the registrant. In this instance the ACVM Group will also contact the main user groups of affected products to advise that the products concerned are not able to be legally used until they are registered.
- Reports of products not updated will also be held by MAF Quarantine Service (MQS) at the border because the importation of unregistered products is illegal under the ACVM Act. Clearance will not be given to any products that have not been updated until the product is approved under the ACVM Act. Products will either be held at the cost of the importer or reshipped.

Prohibition notices

It is expected that there will be a considerable influx of applications for update of products close to 1 July 2004 and that there will be a backlog of

applications. Products where there have been prohibition notices issued will not get any preferential treatment and applications will be considered in the order that they are received, with the notice remaining in force until the registration is approved.

Prohibition notices are issued in line with sections 6 and 8 of the ACVM Act. Notices issued under section 65 to registrants who have not 'updated' products will prohibit any party from **manufacturing, selling and using** agricultural compounds in contravention of the Act. This process will cover all registrants and the New Zealand manufacturers of trade name products (where they may not be the registrant). Prohibition notices will be lifted only once registrants have completed the update process including payment of the appropriate fee. Notices may be varied:

- where there may be several products under the prohibition notice and one is approved, or
- where no application is received and further compliance action is to be taken.

Appeals

Any person who is affected by a prohibition notice may appeal within 14 days to the District Court on the grounds that it is unreasonable. The Court can then vary, rescind or confirm the notice but an appeal does not operate as a stay of the notice or as a variation to the notice.

Active compliance

It is also expected that non-compliant registrants will be placed on an active compliance list and may be visited unannounced by an inspector to ensure future compliance with the ACVM Act.

Compliance process:

For products that are not currently registered but require registration under the ACVM Act by 1 July 2004

A number of trade name products were not subject to regulatory control under the previous legislation (Fertilisers Act, Stock Foods Act, Animal Remedies Act or the Pesticides Act) but are now covered under the ACVM Act. These products were covered by the transitional provisions of the ACVM Act (as long as they were legally existing prior to the start date of the Act on 2 July 2001) for a period of three years.

However, affected products must be either exempted from the requirement for registration (by Regulation) or registered by 2 July 2004 when the transitional provisions expire.

Affected products

The products now covered include things such as plant compound adjuvants (including wetting and sticking agents), pH buffers, drift retardants, and water conditioners.

Most of the products now included in the ACVM Act are approved by exemption via the ACVM Regulations 2001. Where products are covered by an exemption they are not required to be registered. For instance, there will be some products that will have **ALL** of the ingredients included on the appropriate Generally Recognised as Safe (GRAS) list. The trade name product is exempted and would **NOT** require registration. However, if **one or more** ingredients are not yet on the GRAS list and the product is **used around or on food producing crops**, an application for **registration must be approved by 1 July 2004**. After this date, the products will be illegal to manufacture, import, sell or use as they will be outside the transitional provisions of the ACVM Act.

The ACVM Group is using this opportunity to advise all current registrants who may be proprietors of affected products of their obligations.

Class determinations

If you wish to confirm the status of any product, the ACVM Group will undertake class determinations on receipt of an application. The ACVM Group will also be checking details of previous class determinations and contacting anyone who has affected products to advise them of the situation.

Compliance process

Where products are not exempted or registered after 2 July 2004, the ACVM Group will apply a similar compliance process as advised for products that are currently registered but are not updated to the ACVM Act (see page 4). A register of known products will be maintained on the ACVM website so that users can readily identify any products that would be illegal to use.

The ACVM Group will inform MAF Quarantine Services of the need for special vigilance for the types of products affected by the change and require that all imports of such products be held until approval for clearance from the ACVM Group has been issued. This will be done only once a product has been registered or exempted by Regulation – both processes that can take some considerable time.

Prohibition notices

In addition, prohibition notices will be issued to prohibit further manufacture, sale and use of the affected products. There may be a requirement for some proprietors to recall product from the market place.

Affected companies may be placed on a pro-active compliance list. This means that an inspector appointed under the ACVM Act is likely to make unannounced visits to ensure that there are no breaches of the conditions of the prohibition notices issued, and that the company concerned is actively working towards getting the products registered.

Expiry dates on registrations

It is recognised that there will be less time available to update products to the ACVM Act with the expected influx of applications prior to 1 July 2004. With the introduction of a three year expiry date on registrations, the period will be shorter for products if an application is received close to the deadline. This is intended to provide an opportunity for a re-examination of updated products where limited time was available to complete the process and deal with any issues raised.

The proposed expiry dates on registrations will be:

- three years for applications received December 2003, January and February 2004
- two years for applications received March and April 2004
- one year for applications received in May and June 2004.

Where products have an application within the expiry period, the new expiry will be three years from approval of the application. For all other cases registrations will be re-examined prior to reissue of the registration.

Products that now require registration

Some products that are covered by the ACVM Act were not covered under the previous legislation. The products now covered include groups such as plant compound adjuvants (including wetting and sticking agents), pH buffers, drift retardants, and water conditioners.

Most products are already covered by the exemption Regulations but, if they are not, proprietors need to be aware that **the transitional provisions of the ACVM Act expire on 2 July 2004.**

The transitional provisions allowed for any substance that was legally existing to continue to be imported, manufactured, sold or used for a period

of three years following the implementation of the ACVM Act.

The ACVM Group is using this opportunity to encourage any registrants to check any non-registered products to ensure that they do not require registration under the ACVM Act. Registrations must be approved by 2 July 2004 to enable the products to continue to be imported, manufactured, sold or used.

A detailed article in this edition of *AgVetLink* covers the compliance process to be used for unregistered products (that are not exempted) after 2 July 2004 (see page 5).

Any registrants affected are encouraged to discuss concerns with the ACVM Group. Some of these products will also be affected by the HSNO Act and there is room for providing flexibility on labelling for an initial two year period where needed. Registration will require the usual application for registration of a new product, but there may be limited information required where the ACVM Act risks are low.

The ACVM Group will be writing to all parties who have undertaken class determinations for products in this category to remind them of their obligations under the ACVM Act.

Biosecurity approvals

A large number of products have had no reassessment of their biosecurity risk since their original importation. Because registration of a product releases it at the border for biosecurity purposes, it is important that, for a product registered prior to 1999, a new approval is sought from MAF Biosecurity before products containing biological components are updated. To reduce the number of applications on hold at the ACVM Group, remember to renew biosecurity approvals or at least make an application prior to submitting products for update.

Note for registrant companies: change to invoice date for annual fees

Each year the ACVM Group collects annual fees for each registered product and each product of an agricultural compound listed in Schedule 3. This annual charge, paid in advance, is an amount that covers a 12 month period from 1 July to 30 June of any given year.

Historically, this charge has been collected from the issue of invoices in July of each year and monies are collected over the subsequent months. This has resulted in various problems from the non-payment of fees through to part-refunds due to timing of cancellations.

Consequently, in line with section 4(3) of the Agricultural Compounds and Veterinary Medicines (Fees and Charges) Regulations 2002, payment of annual fees will now be required to be paid in advance of 1 July each year. Where payment has NOT been received before 1 July, the trade name products and products listed as agricultural compounds in Schedule 3 will be prohibited from being imported or manufactured and will incur appropriate penalties as described in the ACVM debt management process.

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