



# AgVetLink

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## NZFSA is up and running!

*The integrated New Zealand Food Safety Authority (NZFSA) came into existence on 1 July 2002. It replaces several regimes that were administered by the Ministry of Health (MoH) and the Ministry of Agriculture and Forestry (MAF). The Agricultural Compounds and Veterinary Medicines Group is now part of the NZFSA. The ACVM Act is now the responsibility of the Minister for Food Safety.*

*The NZFSA has a new look, a new location, and a new website (see insert for contact details). However, as Director Debbie Morris says, 'It is business as usual for the ACVM Group'. Every effort will be made to ensure that service to ACVM customers is not disrupted.*

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## Recent events: 1 July 2002

On 1 July 2002 several changes affecting agricultural compounds and veterinary medicines in New Zealand were implemented:

### ■ New Zealand Food Safety Authority

The integrated New Zealand Food Safety Authority (NZFSA), which includes the ACVM Group, began (see article above).

### ■ ACVM (Transitional Provision) Regulations 2002

The ACVM (Transitional Provision) Regulations 2002 came into effect.

The article beginning on page 2 explains how these Regulations affect products.

### ■ ACVM Fees Regulations 2002

The ACVM Fees Regulations 2002 came into effect, changing ACVM fees and charges (see detailed article, page 4).

**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.

## Transfer of animal remedy licences and pesticide registrations to ACVM registrations

*The Agricultural Compounds and Veterinary Medicines (Transitional Provisions) 2002 came into force on 1 July 2002. This has altered the status of virtually all animal remedy and pesticide products that fit the definition of an agricultural compound. If you have any queries, the following should clarify the situation.*

### ANIMAL REMEDIES

#### What is the status of licensed animal remedies?

On 1 July 2002 virtually all animal remedy products were **deemed not to be licensed** under the Animal Remedies Act 1967. At the same time they were **deemed to be registered** under the Agricultural Compounds and Veterinary Medicines Act 1997 with an expiry date of 1 July 2004.

Therefore, animal remedy products are now registered under the ACVM Act but the registrations must be updated before 1 July 2004 or they will expire. In the meantime the products can be imported, manufactured, sold and used under the same conditions that applied to their animal remedy licence, using the existing approved label.

#### What is the procedure for updating a registration?

To update a registration, you apply for a variation in the registration of the product. With the application you must provide a currently correct product data sheet and the content of the label you intend to use on the product. The ACVM Group will process the application and provide you with a revised certificate of registration with an updated list of conditions, and a signed and stamped copy of the approved product data sheet and label content. The certificate, product

data sheet and label content together constitute your updated registration. Once a registration is updated, the 1 July 2004 expiry date no longer applies.

#### When should registrations be updated?

You must update your registration before 1 July 2004. You can apply for a variation to update the registration at any time. However, the purpose of deeming the licences to be registrations under the same conditions was to avoid multiple changes in labels. The ACVM Group recommends that you delay any request to update a registration for at least 12 months so that you might be able to make one label change that meets both the HSNO and ACVM Act requirements.

#### Can product data sheets and existing labels that the ACVM Group already holds be used when updating registrations?

If you have lodged a product data sheet with the ACVM Group you can refer to it and confirm that all the information in it is still current rather than submit a new product data sheet. In all cases there will be changes in the label content, even if it is only to change the reference from the Animal Remedies Act to the ACVM Act. It is anticipated that the new conditions will prompt label changes as well, so reference to the existing label will probably be inappropriate.

#### Does an application for a variation always prompt an update of the registration?

From now on the ACVM Group would prefer to handle any request for a variation as a request to update a registration. However, you may have a specific need to make some changes without prompting a

registration update. Applications for variations of registration without updating the registration will be dealt with on a case by case basis after discussion with the applicant.

#### Do the Regulations alter the status of provisional licences and research approvals?

Provisional licences and research approvals are not affected by the Regulations, nor are the very few animal remedy licences that have a specified expiry date earlier than 1 July 2004. Those licences and approvals continue without change. The expiry date for provisional licences will not be extended beyond 1 July 2004. Any licences will have to be dealt with as provisional registrations under the ACVM Act.

#### Do the Regulations alter the status of a product that has recently been issued an ACVM registration?

There are relatively few products that have been issued an ACVM registration. These registrations are not affected by the Regulations and the 1 July 2004 expiry date does not apply. These registrations are considered to be updated already, so no action needs to be taken.

#### What fees apply to an application for a variation?

As from 1 July 2002, the ACVM Fees Regulations 2002 came into force. This means a change in fees and charges. See the article on page 4 for a detailed explanation.

#### How do the ACVM (Transitional Provisions) Regulations affect the status of products in regard to the Hazardous Substances and New Organisms Act?

The Regulations have no effect on the status of products in regard to

the HSNO Act. Because there were no transitional provisions for animal remedies in the HSNO Act, the notification under the Toxic Substances Act (NOTS) has been used as the legal mechanism to 'capture' a product as a legally recognised substance during the transitional period.

If an animal remedy was not notified to ERMA NZ it may not be a legally recognised substance. If you are in any doubt about whether or not your product is a legally recognised substance, contact ERMA NZ.

If your product is a legally recognised substance in the HSNO transitional period, then the ACVM Group must notify ERMA NZ of an application to vary or update the registration, but approving the variation is not dependent on confirming a HSNO approval.

This means that there will be no delay in processing applications for legally recognised substances. However, applicants will be advised that they must be aware of their responsibilities under the HSNO Act and that they should check with ERMA NZ.

### **PESTICIDES** **What is the status of registered pesticides?**

On 1 July 2002 pesticide products were **deemed to be** registered under the Agricultural Compounds and Veterinary Medicines Act 1997 with an expiry date of 1 July 2004. The pesticide products that are not agricultural compounds (i.e. home garden products, public health pesticides, industrial and household pesticides) were not affected by the Regulations. Registrants have already been advised to notify the ACVM Group whether or not they consider their products to be agricultural compounds.

All pesticides will still have registrations under the Pesticides

Act. Pesticides that are also agricultural compounds will have both pesticide registrations and ACVM registrations. This is necessary because the transitional provisions in the HSNO Act use the pesticide registrations as the legal mechanism by which the products remain legally recognised in the HSNO transitional period. If the registrations were cancelled, the products would become illegal under the HSNO Act.

Therefore, agricultural compound pesticide products are now registered under the ACVM Act, but the registrations must be updated before 1 July 2004 or they will expire. In the meantime the products can be imported, manufactured, sold and used under the same conditions that applied to their pesticide registrations, using the existing approved label.

### **What is the procedure for updating a registration?**

The procedure for updating the registration of pesticide products is the same as that described above for animal remedy products.

### **When should registrations be updated?**

The advice on when to update a pesticide registration is the same as that described above for animal remedy products.

### **Can product data sheets and existing labels that the ACVM Group already holds be used when updating registrations?**

As for animal remedies, if you have lodged a product data sheet with the ACVM Group you can refer to it and confirm that all the information in it is still current rather than submit a new product data sheet.

In all cases there will be changes in the label content, even if it is only to change the reference from the Pesticides Act to the ACVM Act. It is anticipated that the new

conditions will prompt label changes as well so reference to the existing label will probably be inappropriate.

### **Does an application for a variation always prompt an update of the registration?**

From now on the ACVM Group would prefer to handle any request for a variation as a request to update a registration. However, you may have a specific need to make some changes without prompting an update of the registration. Applications for variation of a registration without updating the registration will be dealt with on a case by case basis after discussion with the applicant.

### **Do the Regulations alter the status of provisional registrations and research approvals?**

Provisional registrations and research approvals are not affected by the Regulations. Those registrations and approvals continue without change. The expiry date for provisional registrations will not be extended beyond 1 July 2004. Any registrations will have to be dealt with as provisional registrations under the ACVM Act.

### **Do the Regulations alter the status of a product that has recently been issued an ACVM registration?**

There are relatively few pesticide products that have been issued an ACVM registration. These registrations are not affected by the regulations and the 1 July 2004 expiry date does not apply. The registrations are considered to be updated already, so no action needs to be taken to apply to update them.

### **What fees apply to an application for a variation?**

As from 1 July 2002, the ACVM Fees Regulations 2002 came into force. This means a change in fees and charges. See the article on page 4 for a detailed explanation.

## ACVM Fees Regulations 2002

As of 1 July 2002 the ACVM Group is operating under new fee regulations. Our regulated hourly rate has increased from \$87 to \$108 (excl GST) and there has been a change in the way fees are charged.

Applications will be processed on a cost versus time basis. When an application is submitted, you will be required to submit the prescreen fee of \$364.50. After this you will be sent a fee module sheet and an invoice on the estimated time that it will take to process the application.

The new fee schedule can be found on the website ([www.nzfsa.govt.nz/acvm/publications/fees/index.htm](http://www.nzfsa.govt.nz/acvm/publications/fees/index.htm)). These fees are an estimate of the time it will take to process various types of data. This schedule will be backed up by a time tracking system to confirm the actual time taken.

At the end of the evaluation process, if the actual costs for the time taken for processing are 25% more or less than that invoiced, and the difference is greater than \$150, then an additional charge or refund (as applicable) will be made.

Annual fees will be charged according to the category of use, i.e. food/crop or non-food/non-crop products. The range of annual fees that are due will be \$269.50 - \$405.50. A letter, invoice and product list will be sent out in the next few weeks.

For further information please contact your operations advisor or Sarah Smyth  
phone: 04 463 2553  
email: [sarah.smyth@nzfsa.govt.nz](mailto:sarah.smyth@nzfsa.govt.nz)

## ACVM Amendment Bill

MAF Policy (now NZFSA Policy) has consulted on proposed amendments to the ACVM Act. A discussion paper was issued in April and submissions closed at the beginning of June. A total of 13 submissions were received. Staff will work through the submissions and respond to the comments made. A summary of the submissions received and the NZFSA's responses to those comments will be sent to all submitters and will be made available on the website ([www.nzfsa.govt.nz/acvm](http://www.nzfsa.govt.nz/acvm)).

The submissions will be drawn on in order to propose to Government the policy for amendments to the ACVM Act. Once Government has decided on the policy for the amendments, a Bill to enact the amendments will be drafted. The Bill will then be introduced to Parliament and will be referred to a select committee for consideration. The select committee will provide an opportunity for submissions on the Bill to be made. At the conclusion of the select committee process, the select committee will report back to the House. The Bill will then move through its second and third readings. Once the Governor General signs the Bill it will become an Act.

How quickly policy approval can be gained and the ACVM Amendment Bill moves through its various stages are to an extent dependent on the parliamentary process. Cabinet sets legislative priorities for Bills. At the beginning of each year it decides which legislation is most urgent and what can wait. However, when an election is called the legislative timetable is set aside. Once a new Government is formed, a new legislative programme will be determined.

Most of the areas of concern identified in the discussion paper on the proposed amendments to the ACVM Act are not major policy changes and would not result in significant adjustments to the Act. Many are technical policy changes and others are minor amendments that are needed to correct errors, or changes that can be implemented administratively. Since the repeal of the Animal Remedies Act 1967 and the Pesticides Act 1979, however, there has been no effective legislation to manage environmental and human health risks from agricultural compounds and veterinary medicines not covered by the HSNO Act.

### Website

Recent updates to the ACVM website are:

- *ACVM Standard for GMP*, and *ACVM Guideline for GMP*  
Revised versions for public discussion; send comments to Brian Pidford (see insert for contact details) by **1 September**
- ACVM forms revised to include the NZFSA logo
- Operational policy: Processing applications for registration or for variations in registration in regard to agricultural compounds that may be hazardous substances
- Updated fee schedule

## Processing applications for registration or for varying registrations for trade name products that may be hazardous substances

All applications received by the ACVM Group must now be processed under the provisions of the ACVM Act.

Subsections 21(5) and 27(7) of that Act place obligations on the ACVM Group not to register an agricultural compound trade name product that is also a hazardous substance or new organism unless an approval for the substance or organism has been issued under the Hazardous Substances and New Organisms (HSNO) Act 1996.

The phrase 'an approval for that substance or organism has been issued under the Hazardous Substances and New Organisms Act 1996' if interpreted strictly and literally could mean an approval under Part V of the HSNO Act or regulations made under section 160, which specify that a substance or a group of substances are deemed to have been assessed and approved by the Authority.

Legal advice to the ACVM Group is that where a substance is equivalent to a substance recognised as legally present in New Zealand under the transitional provisions of the HSNO Act, an approval is not required. The ERMA NZ Guidelines state that if a substance or organism is currently present in New Zealand as a legal substance or organism then it is not necessary to make an application for approval. Therefore, if a substance is the same as one covered by the transitional provisions (because it is a registered pesticide or was notified as a toxic substance), then it does not require ERMA NZ approval. Under these circumstances

sections 21(5) and 27(7) of the ACVM Act either do not apply or, if they do, have been satisfied.

Consequently, the following policy shall be applied to the processing of applications to register or to vary a registration of an agricultural compound trade name product that may be a hazardous substance.

Applications for registration of a new trade name product must also include either:

- Reference to the appropriate ERMA NZ approvals; or
- a determination from ERMA NZ that the trade name product is either not a hazardous substance or is legally present in New Zealand under the transitional provisions of the HSNO Act; or
- a non-hazardous substance declaration signed by the applicant, if the trade name product is not a hazardous substance; or
- a declaration that the product is

legally present in New Zealand under the transitional provisions of the HSNO Act.

The application will be notified to ERMA NZ in accordance with section 13 of the ACVM Act. If the application includes only a signed declaration and ERMA NZ advises the ACVM Group that the trade name product is a hazardous substance that is not covered by the transitional provisions of the HSNO Act, the ACVM Group shall complete its evaluation of the application and make its decision. However, it shall advise the applicant that the ACVM registration cannot be issued until there is confirmation from ERMA NZ that the appropriate approvals have been issued.

Where the required information has been provided, the ACVM Group will complete its decision making process under section 21 of the ACVM Act 1997, registering or varying the registration of the trade name product, if appropriate.

### New advisor

**Paul Dansted** has recently joined the ACVM Group as Senior Advisor (Technical Policy). He will be primarily responsible for development of ACVM policy and standards, and will work closely with the Operational Policy Committee and the NZFSA's Policy Group.



Paul holds a Ph.D. in organic chemistry from the University of Auckland. He was previously a senior policy analyst in the Food Group of the Ministry of Health. Although Paul enjoyed this work and all its challenges, he is looking forward to working with the ACVM Group of the new NZFSA.

## Policy for advertising trade name product agricultural compounds

The ACVM Group has developed a policy on advertising trade name product agricultural compounds. Much of the policy is the same as it was under the Animal Remedies and Pesticides Acts. However, some new elements have been added to reflect changes in advertising practices and communication technology.

The policy also reflects changes in the status of products now that some products will be exempt from registration. Even though products are exempt from registration, they must still comply with established advertising practices and not alter the status of the product by presenting it in a manner or making claims that are inconsistent with the registration exemption.

The policy also recognises the fact that parties other than the registrants may be advertising products. These parties must be subject to the same requirements as the registrants to ensure that products are presented in a manner consistent with the conditions of registration or exemption from registration.

The draft policy is available on the ACVM Group's website ([www.nzfsa.govt.nz/acvm](http://www.nzfsa.govt.nz/acvm)).

Comments on the draft should be sent by **1 September 2002** to:

Chris Boland  
Programme Manager  
(Technical Policy)  
Email:  
[christopher.boland@nzfsa.govt.nz](mailto:christopher.boland@nzfsa.govt.nz)

## In-feed and in-water medication label requirements

The efficacy of proven in-feed and in-water medications relies on the animal being treated consuming the quantity of medicated feed or water predicted when the inclusion rate of medication is calculated. In most situations the inclusion rate is calculated by the registrant and expressed as a quantity of medication per kilogram feed or litre water on the label. For prophylactic medications this may be an adequate amount of information because animals undergoing therapy will generally have normal intakes. However, in some cases and in particular if the medication is for therapeutic purposes, this is unlikely to hold true.

If animals have subnormal feed or water intakes, the consequent reduction in medicine intake is likely to have a negative impact on product efficacy, and subsequently on animal welfare. In consequence, the user of the product should have a sufficient amount of information readily available to enable the accurate dosing of animals at all times.

In recognition of this need the ACVM Group has adopted a policy that the labels of all medications delivered in-feed or in-water must contain (as a minimum) the following administration information:

- a dose rate for each label species, e.g. in mg/kg; and
- where feed or water inclusion rates are recommended (amount of product per kg feed or L water), a statement that they are based on the assumption that animals have a certain nominated intake, and should be adjusted as necessary to achieve the required dose rate where intakes vary from that nominated.

Following formalisation of this policy, the labels of all in-feed and in-water medications registered under the ACVM Act will be required to carry the above information. All veterinary medicines and animal remedies that are not currently compliant will be expected to become so prior to 1 July 2004.

### Registration numbers under the ACVM Act

Under the ACVM Act, the numbering of registrations is to continue in the sequence that has been used for products licensed/registered under the Animal Remedies and Pesticides Acts.

The only noticeable difference this will make to applicants is in the registration statement on the label. In order to differentiate products under the Act, the registration number will be prefixed with 'A' for veterinary medicine products and 'P' for plant compound products, e.g. 'Registered pursuant to the ACVM Act 1997, No. A1234' for a veterinary medicine or 'Registered pursuant to the ACVM Act 1997, No. P2468' for a plant compound.

A small number of products already registered under the ACVM Act have not had this prefix added to the registration number on their label content. Affected registrants will be contacted in order to correct this at the next reprinting of their labels.

## Restricted substances and veterinary medicines

As an agricultural country reliant on retained market access, New Zealand must remain responsive to the requirements of overseas trade partners. Some overseas countries including the EU have banned the use of certain substances in, or on, food producing animals. In consequence, animals that have been treated with these substances in New Zealand may not be sold for entry into the human food chain where it cannot be assured that the animals (or their edible tissues) do not enter a market where the substances are prohibited from use on food producing animals. At the moment the substances in question are:

- Chloramphenicol
- Colchicine
- Chloroform
- Nitrofurans (including but not limited to nitrofurazone, nihydrazone, furazolidone, furaltodone)
- Nitroimidazoles (including but not limited to dimetridazole, ronidazole, metronidazole, carnidazole)
- Chlorpromazine
- Dapsone
- Substances with the pyrazolidone moiety within the chemical makeup; for example, but not restricted to, phenylbutazone, ramifenazone, dipyrone
- Arsenilic acid
- Nandrolone

To ensure that the export of any edible product from animals treated with these substances does not occur, the ACVM Group will, from 1 July 2002, no longer approve the registration of products containing these substances with label claims for use in cattle, deer, goats, sheep, llamas, ostriches, emu or fish, unless agreed tagging and tracking programmes were instituted. Trade name products that contain these

New Zealand restricted substances and carry claims for use in species other than these animals will still be considered for registration. Where the potential for off-label use of these products in food animals that may supply edible product for export is considered likely, specific conditions will be placed on the product registration to prohibit such use, unless agreed tagging and tracking programmes were instituted. Of particular concern is the potential off-label use of dimetridazole within the ostrich industry in New Zealand. The Animal Products Group of NZFSA intends to address this issue via additional restrictions on the overseas market access requirements for ostriches.

Products currently registered with claims for use in affected species will be required to remove the claims or demonstrate other means of managing the trade risk. Registrants affected by this notice will be contacted by the ACVM Group to ensure that these requirements are met within the agreed timeframe. If you have any comments or concerns on this issue, please send them in writing by **1 September 2002** to:

Jennie Yee  
Assessor (Technical Standards-  
Veterinary Medicines)  
ACVM Group  
NZFSA  
PO Box 2835, WELLINGTON  
email: jennie.yee@nzfsa.govt.nz

### GMP approvals

Certificates of compliance with Good Manufacturing Practice (GMP) issued to manufacturers after inspections will change under the New Zealand Food Safety Authority (NZFSA). The new certificates will be NZFSA certificates, which will be in the form agreed under the mutual recognition agreement for GMP assessment with the European Community (EC).

However, if the manufacturer being inspected produces products that are registered and exported to the EC, then the GMP certificate issued will be a MAF certificate for the time being. This will be in the agreed format and will include the words:

‘ISSUED UNDER THE PROVISIONS OF THE  
MUTUAL RECOGNITION AGREEMENT  
BETWEEN THE EUROPEAN COMMUNITY  
AND NEW ZEALAND’.

This is being done because the mutual recognition agreement in place is between MAF as the New Zealand competent authority, and the European Commission as the European one. The process of managing the change to recognise the NZFSA as the competent authority will occur within the next 12 months alongside other official assurances. In the meantime, both certificates will have equal validity in New Zealand and they will be phased in as the inspection programme progresses. The existing Animal Remedies Board certificates also remain valid until a new inspection is carried out.

## Continued control of vertebrate pest control products under the ACVM Act

The registrations of vertebrate pest control products have been transferred to ACVM registrations. While the ACVM (Transitional Provisions) Regulations 2002 provide for the ongoing importation, manufacture and sale of these products under their present conditions and labels, the registrations are being reviewed to ensure that the conditions of registration adequately manage the ACVM risk areas.

The ACVM Group considers it essential to maintain a comprehensive control programme without interruption. It is also essential to review present regulatory arrangements to ensure that present controls are necessary and sufficient, and that all the products are controlled adequately, even those that were not scheduled in the Pesticides (Vertebrate Pest Control) Regulations 1983.

The ACVM Group is also concerned that, at least in the short term, there may be difficulty maintaining some aspects of the present programme under the controls that can be imposed under the Hazardous Substances and New Organisms Act 1996.

The important components of the programme that may be put at risk from a food safety perspective are:

- the ability to revoke user approvals;
- the obligation to maintain a compulsory national database of approved users;
- the requirement for users to be confirmed as fit and proper persons before licensing;
- the ability to ensure compliance and enforce ACVM Act conditions.

To ensure continuity in regulatory control the ACVM Group will contact all product registrants and advise them that additional conditions are being applied to the registration of their products. Under section 23 of the ACVM Act, the ACVM Group will impose specific conditions on the importation, manufacture, sale and use of vertebrate pest control products. This will create statutory obligations similar to those imposed under the Pesticides (Vertebrate Pest Control) Regulations 1983. The difference will be that the obligations will be applied directly to the registrations of the products themselves. Inserts must be provided with the products specifying the statutory obligations for distributors, pest control agencies and users.

The conditions will also include a requirement for users to be approved. This will be similar to the present VPC licence but it will be valid only for up to five years. Licensees will have to contact the ACVM Group to convert their

existing licences into ACVM approvals. They will have to show they are competent. This can be done by reference to an approved handler certificate issued under the Hazardous Substances and New Organisms Act 1996, or by reference to the existing VPC training programme. 'Fit and proper person' assessment will still be a requirement, and approvals will be revoked if parties fail to comply with their statutory requirements.

The ACVM Group is working closely with ERMA NZ to ensure that regulatory control is exactly what is needed and does not impose redundant and unnecessary compliance costs. As the approved handler system becomes operational and the VPC substances are transferred into the main framework of the HSNO Act, there are likely to be opportunities to streamline to two systems. Until then the ACVM Group will administer a programme that maintains adequate control.

### Direct credits

To ensure efficient processing of any payments made by direct credit, we ask you to include the following information as a narrative/description so that monies can be allocated quickly and correctly:

- Name of company
- Customer Number
- Invoice Number

If we do not have the correct information, there may be delays in processing applications. If you have any further queries, or wish to pay by direct credit in the future, please contact:

Sarah Smyth  
Coordinator (Business Services)  
Phone: 04 463 2553  
Fax: 04 463 2566  
Email: sarah.smyth@nzfsa.govt.nz



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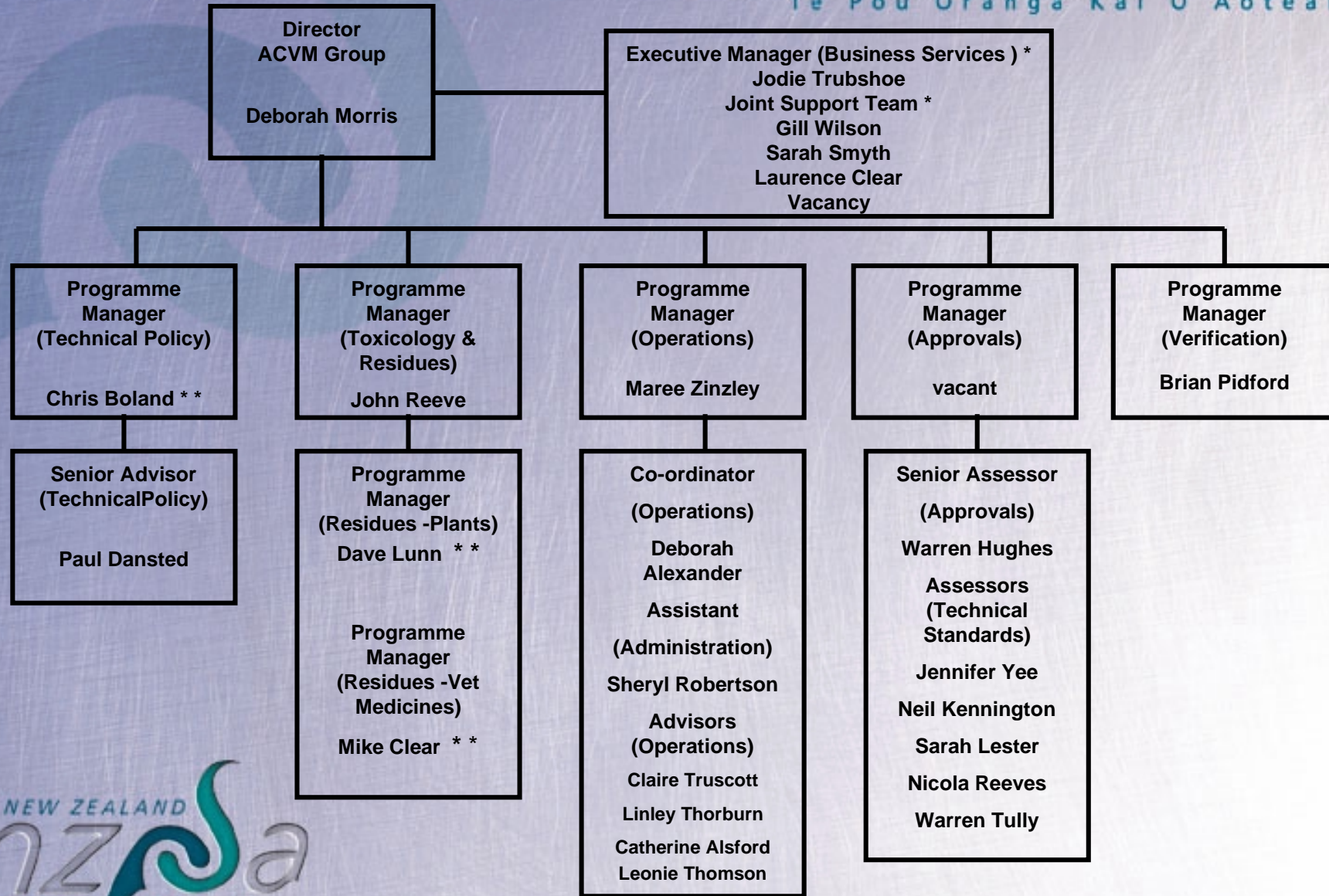
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\* Shared with Director, Dairy & Plant Products Group

\*\* Part time