



# AgVetLink

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## What's coming up

- As this issue goes to print, Maree Zinzley and Brian Pidford are attending the **Registration Liaison Committee meeting** in Canberra. The Committee looks at a range of operational policy issues regarding agricultural and veterinary chemicals and the related compliance activities.
- The ACVM Group is in the midst of workshops covering ACVM Act issues for veterinarians. Most of the feedback has been positive and it is likely that this will become an annual event. There will be a further **'veterinary workshop'** in Wellington in April (date to be decided). Register your interest on the website or with Gill Wilson.
- Warren Hughes and Dave Lunn will attend the **Codex Committee Meeting on Pesticide Residues** in India 16-24 April 2004.
- The ACVM Group has been invited to make a short presentation to the **New Zealand Veterinary Association Branch Summit** on 11 May 2004.
- The next **AVMAC and Industry Liaison meetings** will be held in Wellington on 20 May 2004.
- Debbie Morris (representing New Zealand and Australia) will attend the next **VICH Steering Group** meeting in Japan in May 2004.
- The ACVM Group will have representatives at the **National Fieldays** in Hamilton 16-19 June

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2004. It is viewed as an opportunity to educate people in ACVM Act responsibilities.

- The ACVM Group will be part of the NZFSA team at **'Produce Plus'** in Christchurch 10-13 August 2004.
- The **NZFSA Conference** is planned for 29-30 September 2004 in Wellington. Mark it in your diaries now!

## HAVE YOU UPDATED YOUR PRODUCTS?

**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.

## ACVM Regulations amendment

The Agricultural Compounds and Veterinary Medicines Regulations 2001 were amended on 23 February 2004. The amendment came into force on 25 March 2004.

The amendment provides for the following:

1. Vertebrate and invertebrate attractants and repellents, invertebrate mating disrupters that are not applied directly to animals or plants, and antispasmodics are exempted from registration without being subject to any direct regulatory control;
2. Substances, mixtures of substances or trade name product veterinary medicines that are not registered under the ACVM Act may be used as a veterinary medicine in New

Zealand, subject to the following conditions:

- a. the preparation may be imported only under a permit issued by the Director-General, issued only when there is no equivalent product already registered in New Zealand and the product is needed to ensure the immediate welfare of the animal(s),
- b. the preparation must not contain any substance that is prohibited for use as an agricultural compound,
- c. the preparation must not be used on animals except under the direct care, authority, or prescription of a veterinarian, and
- d. the veterinarian must act in accordance with any applicable

code of practice in force under section 28 of the ACVM Act;

3. The definition of a fertiliser additive has been amended by adding the term 'biological compound' to make it clear that fertiliser additives can be or contain organisms and still be exempted from registration;
4. Attractants applied directly to plants and used solely to attract vertebrates or invertebrates, and invertebrate mating disrupters that are applied directly to plants and used solely to interfere with the reproduction of invertebrates are exempted from registration subject to regulatory conditions; and
5. The addition of 703 substances that are generally recognised as safe to add to oral nutritional compounds or plant compounds.

### ACVM Act amendment

A paper presenting proposals for amendments to the Agricultural Compounds and Veterinary Medicines Act 1997 is being finalised and is expected to be released in April. The paper summarises and takes into account submissions from the MAF discussion paper *Proposed Amendments to the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997*. Stakeholders will be given an opportunity to comment on the proposals. Final proposals will be put to Government for consideration and incorporation into an amendment Bill.

## Advertising policy

As indicated at the recent AVMAC meeting, the ACVM Group facilitated a workshop to discuss the concerns around advertising of prescription animal remedy (PAR) products as set out in the *ACVM Standard for Prescription Animal Remedy Veterinary Medicines*.

In addition to ACVM Group representatives, the meeting was attended by representatives from ARPPA, Agcarm, NZVA and Federated Farmers. The meeting was very useful in understanding the concerns of the various parties and in clarifying the differences between advertising/promotion and the dissemination of information.

### Implementation

The ACVM Group also took the opportunity to present the implementation plans for the PAR standard, particularly how the approvals and any subsequent

sanctions will work (for existing 'traders' and for new entrants). Advertising was then considered in this context.

### Review

While there are still some residual concerns (from NZVA and from Agcarm) in relation to new entrant traders, it was agreed that the standard does not need revision at this time. The working party has agreed to a further meeting in 3-4 months to review implementation and any issues arising; members will also feed back to the ACVM Group details of matters as they arise.

### 'Slice of life' focus

The ACVM Group has undertaken to make sure that there is a focus on the advertising part of the standard in the planned 'slice of life' reviews of the implementation of the standard over the next two to three years.

## VPC products under the ACVM Act

Users of vertebrate pest control (VPC) products are required to be 'approved handlers' under the HSNO Act. A system of authorising Test Certifiers to approve handlers, i.e. persons involved with the manufacture, distribution, transportation, storage, sale and use of VPC products, is being implemented by ERMA New Zealand.

### Different risks

Because the HSNO and ACVM Acts manage different risks, the ACVM Group continues to have a direct interest in the control of the use of VPC products as agricultural compounds for management of risks under the ACVM Act. ERMA New Zealand will be authorising Test Certifiers to carry out activities that impinge on ACVM Group responsibilities. However, not all VPC

products trigger HSNO controls, so the ACVM Group has developed a new standard (see page 4) that includes all of the VPC products and has redesignated them as vertebrate toxic agents (VTAs).

### ACVM criteria

The Group has also prepared the following criteria to be included in the ERMA New Zealand authorisation process to be assured that the ACVM requirements are met. Test Certifiers need to have an understanding of:

- the purpose of the ACVM Act;
- what is meant by risks as defined by the ACVM Group for management under the Act;
- the definitions of an agricultural compound, a veterinary medicine and a VTA product;

- risk control areas relevant to the control programme for the approval of VTA product users (competence of users, application of products by users, secure storage of products, documentation, compliance activities).

### 'Fit and proper person'

While ERMA New Zealand will authorise Test Certifiers, from 1 July 2004 the only part of the approval process that will be handled by the ACVM Group is the 'fit and proper person' component, which is the first step for any person who applies to become an 'approved handler'. The Group will maintain a database of 'fit and proper persons' and supply this information to ERMA New Zealand.

## Historical error policy

Early in 2001 the ACVM Group advised registrants that notifications of historical errors in the information held about a trade name product would be sufficient to correct the error. An application to vary a registration may not be necessary if the error did not affect the level of risks posed by the product and it could be corrected without in-depth assessment. Because there was plenty of time before the deadline for updating registration, such changes could be made without updating the registration. The updating could occur later.

The time for updating is rapidly running out. The ACVM Group is processing an increasing number of applications to update existing registrations and there is no time available to change files separately from updating the registration. Therefore, applicants are advised that the policy of correcting historical errors by notification is no longer operational. Any request to adjust the information held on products will have to be in conjunction with an application to update the registration.

## Updating products

Please be aware that products submitted for updating as from March are unlikely to be processed by 1 July 2004. The ACVM Group is working through updates as quickly as possible; however, with so many applications coming in at the 'tail end' of the time period, we are getting a huge backlog. Companies must not expect them to be completed within 3 - 4 months because the priorities are general applications and review/evaluation assessments. Your only concern should be getting update applications IN THE DOOR to us on or before 1 July 2004. You are not required to have the PDS, label and certificate of updated products by this date.

**PRODUCTS NOT SUBMITTED  
BY THIS DATE  
WILL BE ILLEGAL.**

## Standards update

### Summary of submissions: Draft Standard for Vertebrate Toxic Agents

Fifteen submissions were received on the draft standard for the management of vertebrate toxic agents (VTAs) (the summary of submissions is on the ACVM Group website). Submitters expressed support for the need for controls on the use of these pesticides. However, most submitters were of the opinion that this draft standard under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 duplicates controls that are being developed under other legislation, primarily the Hazardous Substance and New Organisms (HSNO) Act 1996.

Submissions strongly opposed the idea of having **two separate licensing systems** under the two Acts. It was felt that two systems would result in excessive costs and 'red tape'; the result would be detrimental to pest control schemes throughout the country. The opinion was expressed that the ACVM Group and ERMA New Zealand should be able to work together to develop one system that would 'cover' the requirements of both pieces of legislation in terms of licensing, public notification, record keeping and approvals.

The ACVM Group agrees entirely with this intent and is working with ERMA New Zealand to develop efficient regulatory control. The draft standard states the requirements under the ACVM Act so that regulatory action can be taken under that Act. This could not be done if the requirements were imposed under the HSNO Act alone.

The fact that the ACVM registration conditions and HSNO control are virtually the same will make it easier to establish a joint regulatory system that does not require two separate licensing systems or duplicate regulatory costs. At the moment regulatory control is achieved by the ACVM Group under the

Pesticides Act (via the HSNO Act transitional provisions) but this has a limited life. While ERMA New Zealand is establishing its controls and its 'approved handler' system, the ACVM Group will maintain control over the products and users. As the new system becomes operational, the old system will be subsumed into it. However, it is imperative that the new system adequately manages issues such as food residues and provides a basis for export certification as well as protection to the public and the environment.

**Public notification** was an area that drew considerable comment in the submissions. In general, it was felt that requirements under this draft standard duplicated HSNO requirements but that the notification time period (one month) was insufficient.

A few submissions said that public notification should be required only for VTA applications on public land and for aerial applications. Requiring notification for all forms of VTAs would add extra cost disproportionate to the added benefit in public safety.

The ACVM Group accepts these comments and will modify the draft accordingly.

There were differing views regarding **classification** of VTAs. Some thought that the need to classify was debatable because all registered trade name products have controls specified on the label already. Others said that a four-tier classification system (*over-the-counter [OTC], regulated, controlled and restricted*) would be more useful.

The opinion was expressed that decisions on classification should be open, transparent and subject to public consultation. Several submissions said that it was unclear which products were in which category. Some also requested clarification as to which classes of products were subject to the conditions listed in the appendix.

It became obvious that the classification was too limiting given the variability in products. Consequently, the classification will be removed and conditions will be imposed on an individual product basis, with a level of control on distribution, sale and use appropriate for that product. For the most part this will reflect existing controls, but some will have to be adjusted in light of residue and export certification concerns.

The subject of **promoting/advertising** vertebrate toxic agent products was raised in several submissions. Companies involved in the manufacture of such products felt it would be irresponsible not to advise users of the benefits of using their products, circumstances of appropriate use, best practice and so on. The public should know about product successes and failures. It was felt that a ban on promotion would be unacceptable, unworkable and unenforceable. The ACVM Group agrees that the example activities are responsible dissemination of information, not promotion to increase market share.

**Broadifacoum-based products**, which were mentioned in many submissions, generated the most disagreement. While some said the risks in these products should make them Class 2 VTAs, others said present controls are sufficient. This is clearly an area that requires more consideration. However, as stated above, rather than force the products into an ill-fitting class, the ACVM Group will impose conditions on a case by case basis.

Approximately one-third of the submissions questioned the adequacy of the **consultation**. More widespread coverage and a longer period of time for submissions were suggested. It must be noted that this was only the first draft and the ACVM Group intends to work through the issues over time and to allow sufficient dialogue to develop efficient and adequate regulatory control.

### Comments on the revised Standard for Own Use of Agricultural Compounds

The ACVM Group received only one submission on its revised *Standard for Own Use of Agricultural Compounds*. While Federated Farmers of New Zealand supported the apparent intent of the standard, they asked for some clarification and explanation as to why the standard required revision and why it is now called a standard, while previously it was called a 'code of practice'. They also suggested that it would have been easier to comment on if it had included more rationale and specific cases in which the use of generic chemicals by their members was causing problems.

The ACVM Group intentionally limited the standard to the regulatory requirements because it is inappropriate to include rationale and examples in a standard. Nevertheless, an explanation of what has prompted the revision would clearly be beneficial.

#### Why is the standard necessary?

There are many generic chemicals that can be purchased by anyone and safely used as agricultural compounds. Some of them, such as copper sulfate or magnesium oxide, are so common and readily available that it is unlikely that any specific agricultural compound trade name product would ever be marketed. However, with the commencement of the ACVM Act it would have been illegal for these types of substances to be used even though they have been purchased as generic chemicals and used safely for decades.

An exemption to allow common practice was inserted into Schedule 1 of the ACVM Regulations 2001, but it was tied to a condition requiring compliance with an approved code of practice. The ACVM Group developed the code so that parties would know what their obligations were.

#### Is the purchase of generic chemicals for use as agricultural compounds causing problems?

For the most part this practice has not caused any problems. However, even though a number of generic chemicals were widely used by farmers there were still some risks. The ACVM Group developed a code of practice to legitimise common practice, but also to state the expectation that any party who did use generic chemicals as agricultural compounds would be fully responsible for managing those risks.

#### Why did the code of practice have to be revised?

It has come to the attention of the ACVM Group that almost any chemical can now be purchased in its generic form. It has also become apparent that a few people are buying active ingredients (pesticides and veterinary medicines such as antibiotics) that must not be used unless they are in trade name products that have been properly assessed and registered by the ACVM Group. Unfortunately, the original code of practice was too comprehensive and legitimised this practice as well. Hence the revised code (now called a standard) makes it clear that certain substances purchased as generic chemicals could not be used as agricultural compounds.

#### Why has the code of practice been converted into a standard?

The ACVM Group is in the process of developing a range of standards that it can use to measure the acceptability of codes of practice presented to the Group for approval under section 28 of the ACVM Act. This will ensure that any codes that are presented to the Group will be considered in a consistent and transparent manner. In addition, the *Code of Practice for Own Use of Agricultural Compounds* was a statement of expectations rather than an actual code of practice. It did not provide any practical guidance as to how to comply with those expectations.

#### Is the standard in its new form going to be implemented?

Federated Farmers were in support of the intent of the standard. However, they pointed out that it would be difficult for farmers to know which substances could not be used. They suggested that the standard should list any chemical that could not be used. This is impractical but adjustment in the standard is required to assist parties in this regard. The ACVM Group is working with Federated Farmers to develop a practical solution. When this occurs, a second draft standard will be made available for public comment.

### PAR traders – who registers?

There is some confusion regarding registration as a trader in PARs – if the registrant is an organisation rather than an individual, who needs to register?

An organisation can be recognised as trading in PARs. However, it must specify the person who is responsible for PAR trading. That responsible person can specify within their organisation a number of personnel who will carry out particular trading activities. A traceability of these specified personnel must lead back to the principal person.

An organisation with multiple branches and multiple levels of control must have sufficient ACVM Group approved persons to control the specified personnel trading in PARs.

### **Draft Standard for Management of Unregistered Veterinary Medicines Requiring Veterinary Overview**

The ACVM Group has developed a standard for management of some veterinary medicines that are not registered as prescription animal remedies (PARs) but still require veterinary overview. This includes human medicines and specially compounded medicinal preparations that are prescribed by veterinarians for the treatment of animals.

These products are exempt from registration (ref: ACVM Regulations 2001) so they cannot be registered as prescription animal remedies. Nevertheless, they can be used on animals only under the prescription or authority of a veterinarian. This is because they have not been assessed by the ACVM Group in regard to the risks they pose and, consequently, veterinarians play an important part in managing those risks.

The draft standard states the regulatory expectations in regard to the discretionary use of these products and the level of veterinary overview that is expected. For specially compounded medicinal preparations the standard also states the responsibilities of veterinarians when they are either compounding or contracting a third party to compound preparations on their behalf and to their instructions.

The draft is on the ACVM Group website for public consultation. If you wish to comment send your submission by **24 May 2004** to:  
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## **International scene**

### **VICH future**

ACVM Group Director Debbie Morris attended the VICH meeting in Paris in March. The purpose of the meeting was to consider the future of VICH from 2005 when the current five-year workplan finishes. Some key discussion areas were:

- How can existing guidelines be maintained, monitored and reviewed to provide information on costs/benefits and to ensure continuing credibility of the process?
- What are the existing gaps where the development of VICH guidelines could produce a benefit for industry?
- What ICH (human medicine) processes are applicable to the VICH?
- How can the Steering Committee process used to confirm new topics be re-engineered to ensure that the feasibility consideration is carried out adequately?

Conclusions reached at the meeting were:

- The present objectives still apply — the scope (to provide a forum for constructive dialogue between regulatory authorities and the veterinary medicine product industry on real and perceived differences in technical requirements for product registration in EU, Japan, USA...) in the original charter should not be expanded or reduced.
- Any important new topic should be evaluated in accordance with

proposed procedures, whether guidance in the area exists or not.

- The general decision-making process should remain as consensus (VICH meaning is ‘without opposition’) achieved by all parties.
- The level of guidance for production, marketing and control of high quality veterinary medicines should be that which is necessary and sufficient to protect public health, animal health and welfare. There is a risk of driving standards to highest level—providing additional costs with no additional benefits.
- All parties are required to commit the necessary human and material resources for groups and work to proceed to agreed plans. Experts should be chosen for scientific merit, ability to work in a multi-cultural team environment, and skill in negotiation/finding compromises.
- Cost/benefit analyses of the VICH process should include the basis for the analysis including number of companies, geographical distribution, size, responses, numbers of products, guidance involved.
- The Task Force agreed its mandate did not include lists of new topics.

There was some discussion about the frequency and type of meeting required. The preferred option was face-to-face meetings every 6 to 9 months.

### **Controls on VTAs**

**The ACVM Group is working on procedures and processes to handle the changes on controls for vertebrate toxic agents (VTAs). With the transitional provisions covering VPC licences and controls on sale and/or use of VTA products under the Pesticide (Vertebrate Pest Control) Regulations 1983 coming to an end in July 2004, historical and interim conditions of these products will require changes, including labels. Once the first draft of procedures and processes has been completed, affected parties will be consulted on them and on how to proceed forward to minimise time and costs to registrants and the ACVM Group. A letter giving more details on this topic will soon be sent to registrants of VTA products.**

## International Visitors

### OECD

John Reeve, Programme Manager (Toxicology and Residues), attended the OECD pesticides meetings in February. The highlight of the meetings was the adoption of the ten-year vision for the harmonisation of data requirements and regulatory reviews of pesticides.

The aim is to achieve a single review of the data package on a pesticide, which will be picked up by other OECD countries and used for their regulatory purposes without the need to do the review work – the ultimate in work sharing and efficient use of expert resources.

### Toxicology assessors

While in Europe, John visited the University of Surrey to interview students wanting to come and work for ERMA New Zealand and the ACVM Group as toxicology assessors during their professional training year. Two students are required for the 2004/5 year, to replace Steven Johnstone (currently working with ERMA New Zealand) and Richard Dickson-Lowe (working with the ACVM Group). Sion Guy was chosen for ERMA New Zealand, and Andrew Pearson for the ACVM Group.

The employment of Surrey University students has proven to be a valuable resource for the ACVM Group. Andrew will be the eighth student to come and learn the art of regulatory toxicology with us, while doing very useful work in processing appropriate parts of registration applications, MRL setting and adding substances to the GRAS lists.

### APVMA visit

Trevor Doust, Chemistry and Residues Program Manager for the APVMA, visited the ACVM Group on 23 February. He gave a general update on pesticides and veterinary medicines to the entire Group and met with smaller groups for more technical discussions.

Topics covered included:

- New chemistry standard for technical grade active constituents (TGACs)
- Stability requirements
- Cross-referencing rules
- Progress with the APVMA's minor use programme, which was kick-started with the meeting in November and has significant APVMA Board support
- Possibility of mutual recognition of data assessments for chemistry and residues
- Residues (progress in Australia on GLP for field trials)
- Progress with the fipronil/CCA reviews
- New data protection rules for APVMA.

The APVMA's adverse event reporting for pesticides, which just started in January, was also discussed. They have had a reporting system for veterinary medicines in place for some time, and much of their compliance work comes from this, e.g. fipronil.

### VMD visit

The March visit by the Chief Inspector of the VMD, Dr Jason Todd, was the second of two planned visits to align the process of the ACVM Group with that of the VMD in carrying out Quality Assurance/Quality Control (QA/QC) inspections.

These inspections focus on the quality systems of companies manufacturing veterinary vaccines and are used to enable official batch release by the VMD of veterinary biological products into the market in the UK. The VMD has visited New Zealand exporters of these products to the UK on an annual basis.

As a result of a two-year programme of collaborative inspections, the ACVM Group will perform QA/QC inspections on behalf of the VMD under a technical agreement that is being developed between the ACVM Group and the VMD. This will reduce the cost of compliance with UK requirements for exporters into the UK.

## Hui on 1080

**Warren Hughes, Senior Advisor (Approvals), attended a Hui regarding 1080 in Whakatane on 20 and 21 February 2004. The Hui was organised by Landcare Research and was intended to provide a neutral environment and allow participation of Maori to discuss issues over the use of 1080. A number of stakeholders were present and were given the opportunity to express their views on 1080 use.**

**The ACVM Group was one of the stakeholders asked to provide a short presentation. It covered historical and current regulatory requirements on the registration of vertebrate toxic agents.**

**While the Hui did not resolve issues, it did allow stakeholders to present their views in a relaxed environment. It also showed that the community needed more information and consultation over the use of 1080, particularly aerial applications.**

## Staff update

We are pleased to announce that **Jodie Trubshoe** is back on board after maternity leave. However, **Sarah Lester**, Assessor (Technical Standards – Plant Compounds), has begun maternity leave for 12 months. Her replacement is **Claud Warren** who has provided a brief background summary.



'I grew up in the Eastern Cape province of South Africa and attended the Universities of Natal and Pretoria where I obtained undergraduate and postgraduate degrees in agriculture and horticulture. I worked for 15 years in the South African Department of Agriculture as an agricultural extension officer and horticultural scientist. My wife and I moved to New Zealand in May 1999. I completed a postgraduate Diploma in Business Administration and a Master of

Management from Massey University. My interests include listening to music, singing, theatre, sport, walking, counselling, travelling, and enjoying the outdoors. I am looking forward to working within the ACVM Group and being part of the team.'

Also new to the ACVM Group is **Nathan Hinde**, Acting Co-ordinator Business Services (ACVM, Dairy & DIF).



'Born in Auckland, raised in Australia and schooled in Levin, I am now a proud Wellingtonian. After a short stint at Massey University I worked at the Crown Forestry Rental Trust as the Accounts Administrator. I spent six years in the Treaty Claims industry and moved on to the Department of Labour, then to KPMG Consulting. I have many interests, mostly movies, music and sport. I've written a full-length feature film script that wasn't very good and I'm working on another that is much better. I DJ on occasion and have been known to jump on the

microphone for a spot of MC'ing. I play touch rugby and dig snowboarding, mountain biking, skateboarding, stair-surfing and whatever else comes my way. I do some freelance videography, most recently a wedding. (I managed to catch everything...except the ceremony, kiss etc...technical problems...I don't know why they wouldn't just do take two like I said!)

**Kylie Edwards** (Advisor-Operations) has decided to explore new career options and has moved to Melbourne. Her replacement, **Rachel Green**, has just been appointed.

## PATIENCE

As well as coping with new applications plus ever increasing piles of applications to update registrations etc., we are training new staff. Please be patient.

## Compliance update

Although most compliance activity concerns veterinary medicines, the ACVM Group at present is investigating a plant compound — the complaint concerns use of non-registered chemicals on produce.

A significant amount of compliance time is spent investigating complaints about advertising. Companies are making claims that have not been approved. Some claims appear to breach sections of the Fair Trading Act 1986, e.g.

### s10 Misleading Conduct in relation to goods

No person shall, in trade, engage in conduct that is liable to mislead the public as to the nature, manufacturing process, characteristics, suitability for a purpose, or quantity of goods...

### s13 False Representations

No person shall, in trade, in connection with the supply or possible supply of goods or services or with the promotion by any means of the supply or use of goods or services...

(e) Make a false or misleading representation\* that goods or services have any sponsorship, approval, endorsement, performance characteristics, accessories, uses or benefits...

Complaints of this type are referred to the Commerce Commission. Recently the Commission has upheld the ACVM Group's concerns about a company's advertising and has issued a warning to the company with notice that the Commission will be monitoring the marketplace in future.

The ACVM Group is awaiting the outcome of a similar case with a different company, which has also been referred to the Commerce Commission.

\* When the courts are assessing whether or not representations are false and misleading, they consider the consumer's *perception* of what the representation is and not the message that the trader intended to convey.