

Summary of Audit Report

Oral Nutritional Compounds

Background

The purpose of the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, which is administered by the ACVM Group of the New Zealand Food Safety Authority (NZFSA), is to:

- (a) Prevent or manage risks associated with the use of agricultural compounds
 - (i) Risks to trade in primary produce; and
 - (ii) Risks to animal welfare; and
 - (iii) Risks to agricultural security.
- (b) Ensure that the use of agricultural compounds does not result in breaches of domestic food residue standards.
- (c) Ensure the provision of sufficient consumer information about agricultural compounds.

‘Oral nutritional compound’ (ONC) is the generic term used to cover all products designed to provide the routine and special nutritional requirements of both livestock and pets. ONCs fall under the control of the ACVM Act. Most are ‘low risk’ products and are exempt from registration as veterinary medicines under the ACVM Regulations 2001, subject to compliance with conditions laid out in Schedule 4 of the Regulations. The conditions listed in Schedule 4 primarily consist of compliance with labelling and information requirements, confirmation of the product as ‘fit for purpose’, and that any feed additives used are detailed on the Generally Recognised as Safe (GRAS) register.

In 2003 the ACVM Group Director commissioned the NZFSA’s Compliance and Investigation Group (CIG) to carry out an audit of the level of compliance with Schedule 4 requirements by importers, manufacturers and traders of ONCs. The auditor’s focus on labelling requirements and ‘fit for purpose’ status of the products included consideration of the auditees’ knowledge of bacteriological status, the full composition of the product (both active and excipient ingredients), and nutritional profile of relevant compounds. The auditor was also asked to provide recommendations for improvements to NZFSA standards and procedures if required.

The October-November 2003 audit, which was essentially a ‘slice of life’ look at current practice, included consideration of the requirements laid down in the ACVM Act and associated Regulations as well as the *ACVM Draft Standard for Oral Nutritional Compounds*¹. A technical advisor from the ACVM Group accompanied the auditor for some interviews.

¹ Following public consultation, this draft standard was finalised with no significant alterations shortly after the audit was completed.

AUDIT

The key topics

The following emerged as ‘key topics’, i.e. subjects of particular interest, during the audit:

- Labelling requirements
- ‘Fit for purpose’ requirements
- Feed additives and the GRAS (Generally Recognised as Safe) Register
- Suppliers of prescription animal remedies
- Audit of a particular company (name removed)
- Auditee knowledge of ACVM requirements

Labelling requirements

Schedule 4, clause 1 of the ACVM Regulations 2001 outlines labelling requirements. It reads as follows:

They must be supplied with a label containing the following information:

- a) *trade name:*
- b) *the name and address of the producer, if applicable:*
- c) *the name and address of the manufacturer, if applicable:*
- d) *ingredients:*
- e) *directions for use, including the species, type, and class of animal intended to be used for:*
- f) *details of any precautions to be taken to prevent or manage risks described in section 19 of the Act when being used, particularly potential hazards to animals fed with or exposed to them:*
- g) *batch number, if applicable:*
- h) *manufacturing date, if applicable:*
- i) *use by date or expiry date, if applicable.*

Compliance with this requirement varied amongst the auditees.

One auditee specialised in the supply of the base ingredients, some of which could be used as compounds in their natural state, e.g. salts and minerals. The trade name, which was the base ingredient, name and address of manufacturer, and possibly a manufacture date were commonly applied to the bags of these, primarily imported, products. Directions for use were sometimes included and the auditee claimed ignorance as to his clients’ end use of these products.

Another auditee, a manufacturer of pre-mixes used mainly in the primary produce industry, complied with all the labelling requirements with the exception of the ingredients. The auditee in this case listed the active ingredients and was concerned that the disclosure of every actual ingredient would release commercially sensitive information.

The auditor reviewed the New Zealand Petfood Manufacturers Association *Code of Practice for Labelling*. The code of practice incorporates the requirements of Animal Products legislation and the ACVM Regulations. Section 3.5 deals with the ingredients list and section 3.5.5 reads as follows:

Where a food additive belongs to a class commonly described by one of the names set out below, that name may be used in a statement of ingredients to identify that food additive: antioxidants, flavours, humectants, preservatives, vitamins, colours, minerals, food acids, stabilisers, emulsifiers, gelling agents, mineral salts, thickeners.

The code of practice has indicated that the use of class names is acceptable in the pet food industry. The use of class names may also be acceptable in the pre-mix industry.

The ACVM Group has published the *ACVM Draft Standard for Oral Nutritional Compounds*. In discussing the labelling requirements it has suggested that the information on ingredients *must be at least as detailed as is considered common best practice in the feed manufacturing industry for that kind of product. It is expected that the industry sector, in consultation with regulators and consumers, would determine what common best practice is for labelling ingredients.*

‘Ingredient’ is not defined in the ACVM Act, the ACVM Regulations or in the *ACVM Draft Standard for Oral Nutritional Compounds*. There is no reference to standards within the Regulations. The above discussion indicates that the use of class names is likely to be appropriate; however, the Regulations do not indicate what level of specificity is required in the labelling of ingredients.

The auditor recommends that the NZFSA consider amendment of the Regulations to include reference to ACVM standards, or further defines the term ‘ingredients’ to clarify its expectations with respect to labelling of ONCs.

Manufacture date, use by date or expiry date

The Regulations require the above dates to be included on the label information, where applicable. In most cases this condition was met, especially where the product was obviously perishable. One auditee who imports most of his products into New Zealand was adding a ‘best before date’ that he calculated as two years from the date he received the product. The auditor advised that the auditee should be able to demonstrate that this date is appropriate for the products concerned and recommended he make contact with the relevant manufacturers to ensure his dates are technically justifiable.

Batch number

The Regulations require that batch numbers be included in the label information, if applicable. This component was missing in a range of imported products that also did not have a manufacture date, best by date or expiry date.

The *ACVM Draft Standard for Oral Nutritional Compounds* has suggested that there must be adequate information to facilitate investigations of adverse events or non-compliance, including contact information. The standard says, ‘*It must also provide a batch number, delivery reference or both so that the actual product used can be related to the manufacturing process*’.

The Regulations require batch numbers, manufacturing date, use by date and expiry, *if applicable* (auditor’s emphasis) and neither the Regulations nor the draft standard expand in which circumstances it would be deemed to be ‘applicable’. The auditor suggests that if trace back investigations are required, then at least one of the above details is mandatory, with the possible exception of customised, one-off production runs. The auditor suggests that further consideration be given to this requirement with the suggestion that at least one of the details is included and is made a mandatory requirement.

Importer details

The *ACVM Draft Standard for Oral Nutritional Compounds* has suggested that because there is no producer or manufacturer in New Zealand then labels should specify the importer as the person responsible for the product.

In one case of pet food, the larger packets of product were appropriately labelled with New Zealand contact details but space limitations meant smaller packages did not contain importer details. In another case, the importer has placed stickers on all products imported by him to ensure contact details are available for his customers.

The auditor noted that the level of compliance with this standard requirement is variable. Some products contain an 'Australasian' contact, others have website details, while others have only the overseas manufacturer details.

'Fit for purpose' requirements

Schedule 4, clauses 2 and 3 relate to 'fit for purpose' requirements.

- 2 *They must be fit for the purpose of feeding to the species, type, and class of animal specified under clause 1(e).*
- 3 *They are fit for their purpose only if they are used as recommended and do not do any of the following:*
 - a) *produce residues in primary produce that fail to comply with applicable food residue standards set in or under any enactment:*
 - b) *result in toxic reactions causing pain or distress in the animal:*
 - c) *result in malnutrition causing pain or distress in the animal:*
 - d) *contain pathogenic micro-organisms at levels that could cause disease resulting in pain and distress.*

These conditions require a level of knowledge about the nutritional compound and about the nutritional requirements of the animal species involved. The auditees who were importing products had very little personal knowledge about how their product formulations had been determined and how their products fulfilled the nutritional requirements of the target animals.

In one case, imported dog and cat food from the USA was labelled with a statement along the lines that the product met the 'AAFCO nutrient profiles' (Association of American Feed Control Officials) for the dog or cat. None of the other imported ONCs examined contained any information to suggest that the compounds were fit for purpose. All auditees who imported products were asked to explore this requirement with the manufacturers.

A pet food manufacturer and a pre-mix manufacturer both had technical expertise within their organisations, and the pet food manufacturer had a statement on their products indicating their products met the nutrient requirements as established by the AAFCO food nutrition profiles. The pre-mix manufacturer has a nutritionist on staff who, through reference to published nutritional data, research material and own experience, formulates the pre-mixes as required by clients. The company has development protocols that subject formulations to peer review and system audits, and the auditor was satisfied that pre-mixes manufactured by this company should provide adequate nutrients as specified.

The *ACVM Draft Standard for Oral Nutritional Compounds* has suggested that master formulations must indicate what internationally recognised nutrition guidelines were used to ensure that use of the products as recommended would not result in either toxicity or malnutrition. There was resistance to this suggestion by the pre-mix manufacturer because their formulations can be based on New Zealand specific conditions, client specific requirements, and because of the multitude of customised formulations. The auditees were advised to make submissions to the ACVM Group about their concerns with the standard. However, the auditor believes the company has sufficient systems in place to enable compliance with this requirement should it become obligatory.

Feed additives and the GRAS (Generally Recognised as Safe) Register

Schedule 4, clause 5 reads as follows:

Feed additives may be used in oral nutritional compounds only if the feed additives are described in Part A of Schedule 7.

(Feed additive is defined as ‘... a non-nutrient substance added to the feed of animals to improve the preservation, digestion, colour, palatability, texture, or nutritive values of the feed’.)

Part A of Schedule 7 is entitled ‘Substances Generally Regarded as Safe Feed Additives in Oral Nutritional Compounds’. The most up-to-date version of this list is found on the ACVM Group’s website.

Although the pet food manufacturer was aware that feed additives had to be on the GRAS Register, they were not aware that the requirement for compliance was generated from the ACVM Regulations. One importer who has submitted all his product data for Class Determination was aware of the GRAS list, as was the pre-mix manufacturer, but the remaining auditees were not aware of the need to ensure non-nutrient ingredients were included on the GRAS Register.

There were discussions about using some products that have traditional uses as nutritional substances primarily as non-nutrient ingredients to improve palatability, e.g. molasses, and the need to have these included on the GRAS Register. In one case molasses powder is used to improve palatability but this was not included on the GRAS Register at the time of the audit. The powder allegedly had no nutrient value and, while molasses syrup is the traditionally available and common additive in feedstuffs, both should be included in the GRAS Register if being used as feed additives rather than as nutrients in their own right.

The auditor has referred to the ACVM Operational Policy *Classification of Substances as Generally Recognised as Safe (GRAS)* (March 2000), to see whether clarification on the use of common feedstuffs and their derivatives is included. The policy, under section one Background, reads as follows:

The registers provide a practical means of ensuring that regulatory interest focuses on substances that should be of concern either because they do pose hazards or because there is insufficient experience to determine whether or not the substances should be recognised as safe when incorporated into a range of products.

Substances that are widely used to feed animals must logically already be compliant with GRAS requirements. However, the legislation is clear in that non-nutrient substances must be described in the GRAS Register. At least one auditee believes that the addition of these innocuous feedstuffs to the GRAS Register would clog the system and defeat the main objective of the register.

The auditor believes that any attempt to amend the Regulations to exclude the requirement for ‘traditional’ feedstuffs to be on the register could lead to further confusion, in time, over what is considered to be a ‘traditional’ feedstuff. What is widely and commonly used now may change in the future.

The auditor was unable to access the GRAS Register from other jurisdictions to ascertain what approach had been taken and recommends that the ACVM Group examines this issue and provides further clarification in its GRAS policy.

ONCs with non-gras ingredients

Some ONCs contain substances that are not GRAS. Two of these non-GRAS substances, glucosamine and chondroitin, are sometimes ingredients in dog/cat foods. If either of these substances is present at levels higher than would normally occur, the product must be registered and must comply with the conditions of that registration, including ACVM Group approval of label content.

The auditor examined a range of imported ‘senior’ cat and dog foods that contain glucosamine and chondroitin sulphate, and found that several products exceeded the levels permitted without registration.

ONCs with therapeutic or pharmacological substances

Where agricultural compounds that are therapeutic or pharmacological substances are incorporated into an ONC, the agricultural compound must be registered under the Act and the incorporation of the agricultural compound must be consistent with the conditions of registration. There was only one instance of this encountered during the audit.

Audit of a particular company ***

Most auditees during this audit had matters to address to improve compliance with the Regulations, but they exhibited an attitude of cooperation and willingness to carry out any necessary actions with one exception. The auditor experienced an unwillingness to disclose information and cooperate from one auditee who supplies a variety of multiple use products to a range of customers and industries. The auditor believes this auditee would benefit from a targeted audit by ACVM technical staff and further examination of his products. The documented location findings provided to the auditee clearly outlined the requirements of the Regulations and made the recommendation that a further audit be undertaken by the ACVM Group to ensure compliance.

Auditee knowledge of ACVM requirements

Perhaps the most important finding of this audit is the lack of knowledge by auditees of the ACVM Regulations and the relevance to their operations. In the main, compliance with the Regulations was attained vicariously. For example, the labelling requirements are also common sense components that are expected, to some extent, so many products comply with those specifications. Other aspects of the Regulations, such as ‘fit for purpose’ requirements and the need for feed additives to be on the GRAS Register, are not as well known with a resulting lower level of compliance.

At least one auditee (a pet food importer) was not aware of the ACVM Group at all. The importer had been importing product for approximately 4 years and was aware only of Customs and

Biosecurity requirements. The auditor suggests that the ACVM Group makes more information available through the MAF Quarantine Service to ensure that future 'new' importers are aware of the ACVM Group and the requirement for imported ONCs to comply with the ACVM Regulations.

Of the auditees who knew of the Regulations, few had familiarised themselves with the content or attempted to comply with the requirements as specified.

The auditor understands that ONCs are in the lower risk category of veterinary medicines. However, it is suggested that some consideration be given to creating a higher profile of the ACVM Regulations, through publications, to ensure all industry participants are aware of the requirements.

During the audit the auditor viewed pet food for sale in butcher shops, e.g. pet mince, that contained little, if any, labelling information, indicating there is a large sector of relevant industries that are not aware of the requirements.

In addition, the auditor viewed pet food treats, e.g. Purina 'Beggin' strips', which also indicate a wide variance in compliance. While these treats provide some nutritional benefit and are intended only as a treat, they are within the jurisdiction of the Regulations. The majority of these products are imported and information needs to be directed towards the appropriate industry.

The auditor acknowledges the small sample size of auditees may have skewed findings of the audit, but believes it to be fairly representative of the types of businesses involved in ONCs and generally representative of the low level of knowledge regarding the Regulations.

RECOMMENDATIONS TO NZFSA

'Ingredient'

That the NZFSA gives consideration to inclusion of reference to ACVM Standards within the Regulations or considers the further clarification, by definition of the word 'ingredient' to ensure its expectations with respect to labelling of oral nutritional compounds are met.

ACVM Group response

As stated in the audit report, the *ACVM Standard for Oral Nutritional Compounds* has been promulgated since this review was carried out. The ACVM Group intentionally left the specification of common best practice for providing ingredients on labels to the separate industry sectors manufacturing and selling oral nutritional compounds. The standard does not define ingredient. The dictionary definition of ingredient is considered adequate when placed along side the industry guidelines for providing information on labels.

The ACVM Group has approved a code of practice for the manufacture of compound feeds, pre-mixes and dietary supplements sponsored by the New Zealand Feed Manufacturers' Association. This code provides guidelines (section A-10) in regard to providing ingredient information. At this time there is no common agreement that the guideline should be more prescriptive or that the information should be more detailed and comprehensive.

The pet food industry may have a different view of best practice. However, without specific guidelines from that sector, the ACVM Group considers that the guidelines (section A-10) in the existing approved code of practice should be the measure of acceptable practice in regard to the ACVM Regulations 2001 (Schedule 4).

Until the ACVM Act is amended to provide for standards to be approved in addition to codes of practice, the ACVM Group is satisfied that using its standard to measure the acceptability of codes of practice provides sufficient recognition of the standard and sufficient bases for using the standard as a guide to audits or investigations of suspicions or allegations of non-compliance with the ACVM Regulations 2001.

Amending Regulations

That NZFSA gives consideration to amending the Regulations requiring label information to include batch number, manufacturing date, use by date or expiry date as a mandatory requirement to ensure any trace back investigations can ascertain specific production runs of any product of interest.

ACVM Group response

When developing the *ACVM Standard for Oral Nutritional Compounds* the ACVM Group was advised that at least one of those pieces of information is used to identify the manufacture/production of product, but each industry sector is likely to use a different piece. Therefore, there was no single piece of production information that could be prescribed for all the relevant industry sectors. Section A-15 of the approved code of practice specifies the requirement to identify product during all stages of production, storage and delivery to enable trace backs. The actual piece of information that is required is not specified and the Regulations recognise a number of options that would be acceptable, depending on what is common practice for that sector.

The ACVM Group considers that the Regulations as they are written are satisfactory at this time but it will consider a clarification as a possible editorial amendment in its next proposal to amend the Regulations, or if there are standards agreed for any specific part of the industry.

GRAS Register

That the NZFSA examines the inclusion of common feedstuffs used as non-nutrient substances and the legal requirement for such ingredients to be included within the GRAS Register.

ACVM Group response

When the ACVM Group established the GRAS Register it made the policy decision that common feedstuffs as sources of nutrients do not have to be included on the register. Since then some proprietors of oral nutritional compounds have stated that they are using particular feedstuffs for a specific feed additive purpose rather than for a nutritional purpose.

If the ACVM Group sees a feedstuff in a formulation for an oral nutritional compound it will assume it is included for a nutritional purpose. The ACVM Group is not in a position to know which feedstuffs would be used as feed additives, so the Group depends on the applications from proprietors or from industry groups to identify the relevant feedstuffs and the feed additives. The process is straightforward and driven by an industry need. It is satisfied its GRAS approval processes and policies are appropriate.

Company audit

That NZFSA conducts a further compliance audit of a particular company (name removed) to ensure compliance with the ACVM Regulations.

ACVM Group response

The ACVM Group has taken note of the concerns expressed in the audit report regarding a specific company. It was beyond the scope of this 'slice of life review' to audit any party in detail. The ACVM Group will follow-up the findings.

The report has noted aspects of manufacture and sale of oral nutritional compounds that should be monitored. The Group is also reviewing the issues relating to the regulatory control of oral nutritional compounds and the verification of compliance. It will develop an appropriate compliance programme.

Information

That the NZFSA provides more information for dissemination by MAF Quarantine Service to importers of oral nutritional compounds, and considers the publishing of information, through relevant publications, to increase the profile and knowledge of the ACVM Regulations throughout the relevant industries.

ACVM Group response

The ACVM Group agrees that MAF Quarantine Service should have adequate information at hand to regulate the importation of oral nutritional compounds appropriately. The Group will work with MQS to identify and to fill the information needs.

Additional matters raised in the report

The inclusion of particular substances (glucosamine and chondroitin sulphate) was the subject of inquiry. While these substances do occur in some feedstuffs and can be expected to be in oral nutritional compounds, some proprietors are adding additional quantities and either making therapeutic claims or taking advantage of the publicity surrounding the potential therapeutic effect they might have.

The ACVM Group has now published a list of such substances with inclusion levels below which they are considered to be present either for nutritional purposes or are coincidentally present. The ACVM Group is not prepared to enter such substances on the GRAS Register as feed additives because they are not included in the products for any of the feed additive purposes. They must either be coincidental components of feedstuffs (do not have to be on the GRAS Register), supplemented at acceptable levels as nutrients (do not have to be on the GRAS Register) or therapeutic substances (cannot be on the GRAS list) added to an oral nutritional compound.