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Post Office Box 2835
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ACVM STANDARD FOR ORAL NUTRITIONAL COMPOUNDS

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ACVM STANDARD FOR ORAL NUTRITIONAL COMPOUNDS

1 INTRODUCTION

1.1 Scope

This standard covers the requirements for oral nutritional compounds. The group of products that meet the definition of an oral nutritional compound is complex, ranging from bulk animal feeds to specific nutritional supplement preparations sold as trade name products.

This standard provides the requirements based on subgroups of similar kinds of oral nutritional compounds. The relevant subgroups are explained in section 1.3.

1.2 Definitions

Advertisement: Any publication to the community or to any section of the community of any words, whether written, printed, spoken, or in any electronic form, or of any pictorial representation or design or device, used to promote the sale of any agricultural compound. ‘To advertise’ has a corresponding meaning.

Animal: Any living stage of any member of the animal kingdom except human beings. This includes, but is not limited to, any mammal, bird, finfish, shellfish, reptile, insect or invertebrate.

Animal material: Any live or dead animal, or any tissue or other material taken or derived from an animal.

Breaking down and repackaging: To adjust the size, volume, number or weight of an oral nutritional compound and place into an alternative package or container (may also have an alternative label).

Code of practice: Any document issued or approved in accordance with section 28 or the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

Compound feed: A preparation of two or more feeds, or one or more feeds together with feed additives, intended for consumption by animals as a source of feed or nutrients to achieve a nutritional benefit.

Contracting client: Purchaser of an oral nutritional preparation product contracting to have a change in the product such as the incorporation of a prescription animal remedy product.

Controlled copy: A reference document for which:

- responsibility for maintenance, updates, and changes will be undertaken by a limited and defined group of people; and

- all changes and updates will be recorded in writing and maintained for audit.

Dispensing in relation to registered PAR products means:

- to provide such products packaged as per the conditions of their registrations in accordance with a veterinary prescription; or
- to break down into smaller quantities (or volumes), repackage and relabel strictly in accordance with instructions in a veterinary prescription,

‘Filling a prescription’ has the same meaning.

Feed: Edible material prepared and used to feed animals that:

- (a) provides nourishment in the form of energy and for building tissues; and
- (b) contributes to the normal physiological function and metabolic homeostasis of an animal.

Feed additive: A non-nutrient substance added to the feed of animals to improve the preservation, digestion, colour, palatability, texture, or nutritive value of the feed.

Functional nutrient: Substances, composed of biochemical units that are nutrients, that can normally occur in feed commodities that fulfill the definition of providing ‘nutritional benefit’ when included at certain levels in oral nutritional compounds but are also associated with therapeutic or pharmacological properties when fed in quantities exceeding normal dietary intakes.

Generally Regarded As Safe (GRAS) substance: A substance approved and listed in Part A of Schedule 7 of the ACVM Regulations 2001 as generally regarded as safe (GRAS) when added to an oral nutritional compound as a feed additive in accordance with the general conditions applied to substances in Part A.

Label: Any written, pictorial, or other descriptive matter under which the oral nutritional compound is sold and which purports to give some information about the product.

Manufacturer: The person/organisation responsible for the purchase of ingredients, production, formulation, quality control, storage, importation, release and initial distribution of an oral nutritional preparation trade name product.

Nutrient: A nourishing substance given orally, including but not limited to:

- a) a constituent substance of feed that is necessary for, or contributes to, the natural and normal physiological function and metabolic homeostasis of an animal; and
- b) proteins, carbohydrates, fats, oils, minerals, vitamins, water, and their naturally occurring components.

Nutritional benefit: A contribution to the normal physiological function and metabolic homeostasis of an animal achieved by the oral provision of nutrients.

Nutritional preparation: A compounded mix of nutrients or nutrients and feed additives.

Oral nutritional compound: A substance ingested by an animal as feed, or a nutritional preparation intended for oral administration to an animal to achieve a nutritional benefit.

Pharmacological substance: A non-nutrient substance that modifies a physiological function of an animal

Prescription: A written instruction from a veterinarian specifying a particular animal remedy to be administered to a specified animal or group of animals at a specified rate and frequency, and including specific written instructions to the person responsible for the animal(s) regarding warnings and/or associated care. Only veterinarians may issue a prescription for a registered PAR veterinary medicine.

Prescription animal remedy (PAR): A veterinary medicine registered under the ACVM Act with a condition that limits sale to a registered trader in prescription animal remedies, a veterinarian, or to a person in possession of a relevant, bone fide veterinary prescription or authorisation from a veterinarian.

Producer: For the purpose of this standard, the person with overall responsibility for the oral nutritional compound product.

Promotion: To encourage the sale of an oral nutritional compound.

Relabelling: To transfer the relevant label information (provided with the product before breaking down and repackaging) to the package or container in which the oral nutritional compound will be supplied

Sale: Includes barter, and also includes offering, exposing, or attempting to sell, or having in possession for sale, or sending or delivering for sale, or causing or allowing to be sold, offered, or exposed for sale in New Zealand; and also includes:

- a) Delivering or disposing of by way of gift, loan, or otherwise; and
- b) Giving or distributing, in the course of business, as a sample or otherwise, without charge.

‘General sale’ means to make available to the public at large.

Therapeutic substance: For the purpose of this standard, a non-nutrient substance designed to prevent, treat, or cure a disease or abnormal physiological condition. It does not include nutrients designed for oral administration to prevent or treat subnormal levels of nutrients, unless the claims made are to provide immediate resolution in clinically ill animals of nutrient deficiencies characterised by pain or distress.

Trade: In oral nutritional compounds includes wholesale and retail sales transactions as well as distribution, transport and storage. ‘Trader’ has a corresponding meaning.

Trade name product: The name under which a product is identified for sale.

Veterinarian: A person currently registered as a veterinary surgeon under the Veterinarians Act 1994.

Veterinary authorisation: A written approval from a registered veterinarian to a person to hold particular PAR veterinary medicines in anticipation of:

- their incorporation into other products (e.g. animal feeds) to be used under prescription; or
- their use under operating instructions issued by a registered veterinarian.

1.3 Subgroups of oral nutritional compounds

Oral nutritional compound is the generic term used to cover all products designed to provide the routine and special nutritional requirements of both livestock and pets.

For the purposes of the ACVM Act, oral nutritional compounds are considered to be veterinary medicines because they are used in the direct management of animals. This does not mean that they are what is commonly known as medicines or drugs. If therapeutic or pharmacological claims are made about a product, making it a medicine or drug, then it is not just an oral nutritional compound. The only claims about an oral nutritional compound that may be made are ones that relate to achieving a nutritional benefit either by:

- providing normal dietary levels of nutrients; or
- making nutrients more available; or
- supplementing any of the nutrients.

However, the product would still be an oral nutritional compound, and not a medicine or drug, even if general improved health claims that can be related to better nutrition are made.

The word 'feed' refers to products for animal consumption. While it is common practice to refer to pet foods, these are considered to be feeds in this standard because they are not for human consumption. The word 'food' is not used in this standard to refer to oral nutritional compounds because food refers to products for human consumption. Nevertheless, products for pets can and are likely to be marketed as pet foods.

Oral nutritional compounds are divided into two subgroups, based on whether or not a product is formulated from separate ingredients:

- oral nutritional preparations; or
- feed commodities.

1.3.1 Feed commodities

Feed commodities can be used directly as animal feeds without any processing. They are fed to animals on their own without being mixed with any other ingredient before they are offered for sale (i.e. they are not compounded or manufactured into oral nutritional preparations). Feed commodities include grass

and other crops, grain, seeds, meat, milk, eggs etc. Human foods and food by-products can also be used as feed commodities.

Feed commodities of plant origin can be used as feed either before harvesting, as in grass or crops (standing feeds), or after harvesting as in hay, silage, unprocessed grain, etc.

Feed commodities are often used as raw materials in the manufacture of oral nutritional preparations, particularly in compounded feeds. When used as ingredients in oral nutritional preparations they are subject to the same specifications in this standard as any other ingredient.

1.3.2 Oral nutritional preparations

Oral nutritional preparations are products compounded or manufactured from more than one ingredient. They include:

- compounded feeds;
- premixes;
- other nutritional supplements.

Compounded feeds can be made of animal material, plant material or both. They can also contain additional nutrients in the form of supplemented protein, carbohydrates, fats, vitamins and minerals. They can also contain feed additives. The definition of a feed additive is limited to substances that make the product more effective as an oral nutritional compound.

Compounded feeds can be sold either as bulk livestock feeds or packaged feeds.

Premixes consist of preparations of nutrients, vitamins, minerals and possibly feed additives prepared in concentrated form and sold for mixing with feed commodities or compounded feeds to create a formulated diet.

Other nutritional supplements consist of preparations of nutrients and other chemical substances (including feed additives) sold as products to be administered orally to enhance nutrition. They are true supplements to a diet rather than a component in a formulated feed as in premixes.

1.3.3 Addition of therapeutic or pharmacological substances

Apart from standing feeds, the other oral nutritional compound subgroups can have therapeutic or pharmacological substances added. If such substances are added, the product is not strictly an oral nutritional compound. Therapeutic and pharmacological substances added to feeds are not feed additives.

There are substances that normally can be found in animal or plant material that are believed to have either therapeutic or pharmacological activity. They are not classified as nutrients (i.e. essential for nutrition in their undigested form) but may be considered 'functional nutrients' in some cases. The intentional inclusion of these substances in an oral nutritional preparation at levels that exceed the amount coincidentally present, along with claims that cannot be justified as solely achieving a nutritional benefit, will change the definition of the product from strictly an oral nutritional preparation to a therapeutic or pharmacological preparation.

Where oral nutritional compounds contain ingredients that could be considered to be ‘functional nutrients’, the ACVM Specified Requirements Products Standard and Guideline Oral Nutritional Compounds with Known Therapeutic Uses (Functional Nutrients) +/- Non-Gras ingredients” and the ‘Register of Allowable Nutrients with Known Therapeutic Uses in Exempt Oral Nutritional Compounds should be consulted. (See <http://www.nzfsa.govt.nz/acvm/registers-lists/register-nutrients.htm>).

Whether or not the product then requires additional regulatory control depends on other factors as explained in the following section. Some of these substances can be found in the list of feed additives in Schedule 7 Part A. However, the substances must be added for a feed additive purpose.

1.3.4 Regulatory control of oral nutritional compounds offered for sale

All products that are strictly oral nutritional compounds are exempt from registration under Regulation 8 of the Agricultural Compounds and Veterinary Medicines Regulations 2001 as long as the products comply with Schedule 4 of those Regulations.

For regulatory control purposes oral nutritional preparations can be further grouped (see figure 2) in regard to the following factors:

- formulation of the product;
- GRAS status of the feed additives in the formulation
- the claims made about the product
- the inclusion of registered trade name products and whether the registered products are identified or not
- the intention to offer the product for general sale or not; and
- the inclusion of unregistered therapeutic or pharmacological substances or trade name products.

The nature of the regulatory control and the status under Regulation 8 and Schedule 4 depends on the grouping of a product.

Group 1 includes the feed commodities. They are not manufactured into formulated mixtures. They consist of a single ingredient and are sold as commodities rather than trade name products.

Group 2 includes oral nutritional preparations containing only nutrients and GRAS feed additives and for which no therapeutic or pharmacological claims are made. This group most closely fits the definition of an oral nutritional compound in the ACVM Regulations 2001.

Group 3 products are similar to Group 2 except they contain one or more feed additives that have not been approved as GRAS.

Groups 4, 5 and 6 include oral nutritional preparations containing nutrients, feed additives and one or more registered trade name products. The added products could be registered for over-the-counter sale or prescription only sale and would make some therapeutic or pharmacological claims. This makes them therapeutic or pharmacological preparations rather than strictly oral nutritional preparations.

Group 4 includes compounded products that are not offered for general sale. The inclusion of the registered trade name product is at the request of a specific contracting client and the product is prepared for and sold only to that client. Allowing this practice recognises the skill and expertise of manufacturers to compound products more safely and more accurately than the general public. For example, a client may ask a feed manufacturer or a premix manufacturer to add a registered coccidiostat trade name product to their (Group 2 above) feed or premix. Group 4 also includes products that are compounded under the prescription of a registered veterinarian.

Group 5 includes products that are combinations of oral nutritional preparations and registered therapeutic/pharmacological products that are offered for general sale. The products are offered for sale with label content that includes the full identity of the added registered trade name product, including its trade name, ACVM registration number and the label information normally provided with that product. If this information is not provided in the label content and the product is offered for general sale, it is included in **Group 6**.

Group 7 includes products that are a combination of oral nutritional preparations and unregistered therapeutic or pharmacological substances.

1.4 References

Agricultural Compounds and Veterinary Medicines Act 1997

Agricultural Compounds and Veterinary Medicines Regulations 2001

2. REQUIREMENTS FOR ORAL NUTRITIONAL COMPOUNDS

2.1 Feed commodities/oral nutritional preparations not sold

Standing feed commodities and harvested feed commodities are exempt without conditions from registration under the ACVM Act. Oral nutritional preparations prepared by a person to feed to their own animals (i.e. not sold to any other person or used in a way that allows other people or animals to come into contact with them) are also exempt from registration.

However, there is always the possibility that feed commodities or home milled feeds may have been contaminated with substances that could cause harm to the animals exposed or result in violative residues in the animal products (meat, milk, eggs, honey, etc.) harvested from those animals. While there is no need to register the feed, there is a moral obligation to ensure that the feed will not cause harm to the animals exposed. There are also statutory obligations to:

- protect the welfare of the animals; and
- ensure that there are no violative residues in the animal products.

Parties should take due care to determine the production history of feed commodities prior to feeding them to animals or using them in home milling feeds. There may be a history of contamination or intentional application of chemicals or pesticides. Appropriate steps must be taken to keep animals away from the feed commodities until they can be fed safely or, in the case of possible residues, ensure that animal products are not harvested from those animals until violative residues are unlikely to occur. Failure to do so may result in offences under the Animal Welfare, Animal Products and Food Acts.

2.2 Manufactured oral nutritional preparations exempt

Most oral nutritional preparations are exempt from registration if the following conditions are met (Ref: Regulation 8 and Schedule 4 of the Agricultural Compounds and Veterinary Medicines Regulations 2001).

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.

They must be fit for the purpose of feeding to the species, type, and class of animal specified under clause 1(e). 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.

Agricultural compounds that are therapeutic or pharmacological substances or preparations may be incorporated into oral nutritional compounds only if:

- a) they are registered under the Act; and
- b) the incorporation is consistent with any conditions of their registration.

Feed additives may be used in oral nutritional compounds that are not registered only if the feed additives are described in Part A of Schedule 7 of the Agricultural Compounds and Veterinary Medicines Regulations 2001.

Given the requirements in the ACVM Regulations 2001, Group 2 products do not have to be registered but they must comply with Schedule 4. They are not subject to good manufacturing practice (GMP) approval. However, suspicions and allegations of non-compliance with Schedule 4 will be investigated and may result in a remedial action inspection programme and possibly prosecution. Whether supplied packaged or in bulk form they must be provided with the prescribed information and be fit for purpose.

Group 3 products must be registered because they contain substances that are not approved as GRAS. To avoid this regulatory requirement the relevant feed additives could be proposed for inclusion in the list of GRAS feed additives. Requests to add a feed additive to the list should be sent to the ACVM Group.

Generally speaking, oral nutritional compounds must not contain any therapeutic or pharmacological substances, including substances with therapeutic properties in concentrations intentionally greater than what coincidentally occurs in the feed commodities used as ingredients. No therapeutic or pharmacological claims must be made about the product, either as part of the label information or in any advertisement or promotion of the product. However, the Regulations provide some circumstances in which registered therapeutic or pharmacological products could be added without jeopardising the exemption from registration; these are reflected in the regulatory requirements of Groups 4, 5 and 6.

Group 4 products do not have to be registered as long as the added product is registered. The incorporation of the registered product must be consistent with the

conditions of registration for the added product. In all respects other than the addition of the registered product, the oral nutritional compound component of the compounded product must be consistent with a Group 2 product. Under normal circumstances the manufacture of Group 4 products is not subject to GMP approval.

Because products in Group 5 provide the identity and relevant label information of the added registered trade name product, they do not have to be registered but

- the oral nutritional preparation component must be consistent with a Group 2 product;
- the incorporation of the registered product must be consistent with the conditions of registration of that product;
- the identity and label information on the added product must be provided with the compounded product.

Manufacture of Group 5 products is not subject to GMP approval. However, suspicions and allegations of non-compliance with Schedule 4 or the conditions of registration of the added product will be investigated and may result in a remedial action inspection programme and possibly prosecution.

There is not a requirement for GMP approval for the manufacture of compounded products in Groups 2, 3, 4 and 5. However, the ACVM Group has a particular concern about the safe and appropriate incorporation of therapeutic or pharmacological products into oral nutritional preparations, with particular regard to prescription animal remedy (PAR) veterinary medicines. Manufacturers should also be concerned about maintaining the exemption status of Groups 2, 4 and 5 type products when they are all manufactured in the same premises. Suspicions and allegations of non-compliance will be investigated and manufacturers will have to show that their manufacturing procedures are appropriate and effective.

The oral nutritional preparation products and those components of compounded products must comply with the Regulations. The incorporation of registered trade name products must comply with the conditions of registration for those products. In addition, adequate measures must be taken to ensure the production processes are separate and secure. Manufacturers involved in the production of products in different groups should consider obtaining GMP approval from the ACVM Group to be able to provide assurances of compliance for all their products.

The information on the added registered product is not provided in the label content of a compounded product in Group 6, so these products are considered new products and require separate registrations. They are also subject to GMP approval. The same is true for products in Group 7 because they contain unregistered therapeutic or pharmacological substances. The exemption in the ACVM Regulations 2001 does not apply to products in Groups 3, 6 or 7.

The prescribed requirements are expressed in a generic way and must be interpreted correctly for the different subgroups of oral nutritional preparations and for parties involved in different activities such as importation, manufacturing, or selling products. The requirements can be grouped according to who must comply with or meet the requirements:

- Manufacturing requirements
- Importing requirements (section 4 below)
- Trading requirements (section 5 below)
- Use requirements (section 6 below).

3 MANUFACTURING ORAL NUTRITIONAL PREPARATIONS

Export-only oral nutritional compounds are not subject to this standard, Regulation 8 or Schedule 4. However, they must be either:

- identified as ‘export-only’ and manufactured separately; or
- manufactured in compliance with this standard and the Regulations.

Oral nutritional preparations are commonly divided into feeds, premixes and nutritional supplements. Manufacturing requirements for each of these are slightly different.

3.1 Manufacturing of compounded feeds (pet foods and other animal feeds)

3.1.1 Responsibility

When the manufacturer is the producer of the product, he/she is responsible for ensuring that the product complies with the prescribed requirements for oral nutritional compounds exempt from registration. If the manufacturer is preparing the product under contract to the producer, then the producer is responsible and must make the product specifications and manufacturing directions clear in the contract. If there is any variation to this, the areas of responsibilities must be specified in the manufacturing specification. The following requirements refer to the manufacturer as the producer. If this is not the case, the requirements should be read as pertaining to the person specified as responsible.

3.1.2 Labelling

The manufacturer must ensure that the product is adequately labelled when it is offered for sale. The ‘label’ is all the information provided with the product at the point of sale and is not limited to the information on or attached to the package.

Bulk feed and packaged/labelled feeds must be sold with the prescribed information. It is acceptable for the information relating to bulk feed to be provided in a detached document, but it must be provided with the consignment of feed. The information must be presented to the person with the overall responsibility for feeding the animals. This may mean that, in a vertically integrated operation or in one with multiple production locations, the information can be provided to the appropriate manager who specifies the feeding instructions to the individual farm operators if the farm operators are only following that manager’s feeding instructions. However, if this is the case, the production systems must be robust enough to ensure the specified feed gets fed to the right animals, especially if the feed is a compounded product in Groups 4, 5, 6 or 7.

There must be adequate information to facilitate investigations of adverse events or non-compliance. The contact information should reflect the arrangements in the contract and identify the person(s) responsible for the product. It must also provide a batch number, delivery reference or both so that the actual product used

can be related to the manufacturing process. What is appropriate may vary for different kinds of oral nutritional preparations. What is provided should be what is commonly used in the manufacture, distribution and sale for that kind of product.

There must be adequate information to allow the product to be used safely and appropriately, and before it deteriorates.

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. Manufacturers would be expected to provide at least that level of information.

3.1.3 Production to specifications

The compounded feed when offered for sale must conform to the master formulation and have been manufactured according to the manufacturing specifications.

Manufacturers must not include any feed additive that is not listed in Part A of Schedule 7 of the Agricultural Compounds and Veterinary Medicines Regulations 2001, unless they have confirmed that the substance has been or is being recommended for inclusion in that Schedule. Some substances with therapeutic properties may fit the definition of a feed additive and be included in Schedule 7. However, inclusion in the Schedule does not justify making any therapeutic or pharmacological claims about a substance or products containing that substance. If such claims are made, the product is no longer strictly an oral nutritional preparation and may have to be registered, depending on what product group it falls into.

The records of the development of the master formulations must indicate what internationally recognised nutritional guidelines were used to ensure that use of the product as recommended would not result in either toxicity or malnutrition. Where the formulation deviates significantly from the nutritional guidelines, the records should include the technically justifiable rationale for the differences. Failure to identify the technical basis for inclusion rates and acceptable quality characteristics of ingredients will be considered as taking insufficient care to comply with the Agricultural Compound and Veterinary Medicines Regulations 2001.

It is the responsibility of the manufacturer to have reasonable checks in place and take due care to ensure that the raw materials used to manufacture the product were fit for purpose, either:

- being free of hazards; or
- subsequently processed and incorporated into the product so that they do not cause toxicity, physical damage, malnutrition, violative residues or are a source of pathogenic organisms.

Animal material used in the manufacture of compounded feeds must comply with the requirements of the Animal Products Act 1999.

The manufacturer must document the production process, specifying actions taken during manufacture to ensure that the product met specifications and was fit for purpose. Areas of responsibility must be specified, and production systems and instructions kept current. It is expected that the manufacturing process (from specification of master formulation through packaging, labelling and dispatch) would be subject to a documented quality system, using controlled copies of the quality system or operational manual if necessary.

There must also be contingency plans in the quality system of operational manuals to recall defective product or mitigate adverse effects.

Where products in more than one product group are manufactured in the same premises, the manufacturing systems must be kept separate and secure. While GMP approval from the ACVM Group may not be required, manufacturers involved in producing products in Groups 4 and 5, or in different groups in the same premises, should consider obtaining GMP approval from the ACVM Group to support assurances of compliance.

Manufacturers must not manufacture feeds in Groups 3, 6 or 7 unless they are registered trade name products.

Feeds in Group 4 in excess of that required by the contracting client or in the veterinary prescription should not be stored on the premises. If this must happen, then the feed must be:

- stored in a contained and secure area; and
- authorised by the prescribing veterinarian or specified in the client/manufacturer contract.

The product must not be released to any person other than the contracting client, the prescribing veterinarian, the person specified in the veterinary prescription, or their bone fide agent, whichever is appropriate.

Unregistered therapeutic and pharmacological substances must not be held on the manufacturing premises unless it is specified as part of the ACVM manufacturing approval. If a manufacturer holds registered PAR veterinary medicines in stock in anticipation of veterinary prescriptions, the manufacturer must either:

- be a trader registered with the ACVM Group; or
- have an authorisation from a registered veterinarian who is prepared to accept the responsibility for the overview of the storage.

To maintain the status of exemption from registration of their products, manufacturers must not stock non-GRAS substances, unregistered therapeutic or pharmacological substances or registered therapeutic or pharmacological trade name products on the premises unless those stocks are necessary for the manufacture of:

- registered products in Groups 3, 6 or 7; or
- the compounding of products in Group 5; or
- there is an authorisation from a registered veterinarian in anticipation of particular prescriptions.

The holding of registered therapeutic or pharmacological trade name products in anticipation of a possible contract to manufacture a product in Group 4 is strongly discouraged. The specification of the registered product should come from the contracting client or at least the purchase of the products should be tied to a specific client contract.

3.2 Manufacture of premixes

3.2.1 Responsibility

When the manufacturer is the producer of the product, he/she is responsible for ensuring that the product complies with the prescribed requirements for oral nutritional compounds exempt from registration. If the manufacturer is preparing the product under contract to the producer, then the producer is responsible and must make the product specifications and manufacturing directions clear in the contract. If there is any variation to this, the areas of responsibilities must be specified in the manufacturing specification. The following requirements refer to the manufacturer as the producer. If this is not the case, the requirements should be read as pertaining to the person specified as responsible.

3.2.2 Labelling

The manufacturer must ensure that the product is adequately labelled when it is offered for sale. The 'label' is all the information provided with the product at the point of sale and is not limited to the information on or attached to the package.

Labelling must make it clear that the product must not be fed directly to animals but incorporated into feeds according to the use instructions. The label must include adequate mixing instructions and warnings about the consequences of not mixing thoroughly.

Premixes must be sold with the prescribed information. The information must be available to the person with the responsibility for incorporating the premix into the feed.

There must be adequate information to facilitate investigations of adverse events or non-compliance. The contact information should reflect the arrangements in the contract and identify the person(s) responsible for the product. It must also provide a batch number, delivery reference or both so that the actual product used can be related to the manufacturing process. What is appropriate may vary for different kinds of premixes. What is provided should be what is commonly used in the manufacture, distribution and sale for that kind of product.

There must be adequate information to allow the product to be used safely and appropriately, and before any specified expiry date.

Information on ingredients must be at least as detailed as is considered common best practice in the premix 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. Manufacturers would be expected to provide at least that level of information.

3.2.3 Production to specifications

The premix when offered for sale must conform to the master formulation and have been manufactured according to the manufacturing specifications.

To maintain the status of exemption from registration, manufacturers must not include any feed additive that is not listed in Part A of Schedule 7 of the Agricultural Compounds and Veterinary Medicines Regulations 2001, unless they have confirmed that the substance has been or is being recommended for inclusion in that Schedule. Some substances with therapeutic properties may fit the definition of a feed additive and be included in Schedule 7. However, inclusion in the Schedule does not justify making any therapeutic or pharmacological claims about a substance or products containing that substance. If such claims are made, the product is no longer strictly an oral nutritional preparation and may have to be registered, depending on what product group it falls into.

The records of the development of the master formulations must indicate what internationally recognised nutritional guidelines were used to ensure that use of the product as recommended would not result in either toxicity or malnutrition. Where the formulation deviates significantly from the nutritional guidelines, the records should include the technically justifiable rationale for the differences. Failure to identify the technical basis for inclusion rates and acceptable quality characteristics of ingredients will be considered as taking insufficient care to comply with the Agricultural Compound and Veterinary Medicines Regulations 2001.

It is the responsibility of the manufacturer to have reasonable checks in place and take due care to ensure that the raw materials used to manufacture the product were fit for purpose, either:

- being free of hazards; or
- subsequently processed and incorporated into the product so that they do not cause toxicity, physical damage, malnutrition, violative residues or are a source of pathogenic organisms.

Animal material used in the manufacture of premixes must comply with the requirements of the Animal Products Act 1999.

The manufacturer must document the production process, specifying actions taken during manufacture to ensure that the product met specifications and was fit for purpose. Areas of responsibility must be specified, and production systems and instructions kept current. It is expected that the manufacturing process (from specification of master formulation through packaging, labelling and dispatch) would be subject to a documented quality system, using controlled copies of the quality system or operational manual if necessary.

There must also be contingency plans in the quality system of operational manuals to recall defective product or mitigate adverse effects.

Where products in more than one product group are manufactured in the same premises, the manufacturing systems must be kept separate and secure. While GMP approval from the ACVM Group may not be required, manufacturers

involved in producing different groups in the same premises should consider obtaining GMP approval from the ACVM Group to support assurances of compliance.

Manufacturers must not manufacture premixes in Groups 3, 6 or 7 unless they are registered trade name products.

Unregistered therapeutic and pharmacological substances must not be held on the manufacturing premises unless it is specified as part of the ACVM manufacturing approval. If a manufacturer holds registered PAR veterinary medicines in stock in anticipation of veterinary prescriptions, the manufacturer must either:

- be a trader registered with the ACVM Group; or
- have an authorisation from a registered veterinarian who is prepared to accept the responsibility for the overview of the storage.

To maintain the status of exemption from registration of their products, manufacturers must not stock non-GRAS substances, unregistered therapeutic or pharmacological substances or registered therapeutic or pharmacological trade name products on the premises unless those stocks are necessary for the manufacture of:

- registered products in Groups 3, 6 or 7; or
- there is an authorisation from a registered veterinarian in anticipation of particular prescriptions.

3.3 Manufacture of other nutritional supplements

3.3.1 Responsibility

When the manufacturer is the producer of the product, he/she is responsible for ensuring that the product complies with the prescribed requirements for oral nutritional compounds exempt from registration. If the manufacturer is preparing the product under contract to the producer, then the producer is responsible and must make the product specifications and manufacturing directions clear in the contract. If there is any variation to this, the areas of responsibilities must be specified in the manufacturing specification. The following requirements refer to the manufacturer as the producer. If this is not the case, the requirements should be read as pertaining to the person specified as responsible.

3.3.2 Labelling

The manufacturer must ensure that the product is adequately labelled when it is offered for sale. The 'label' is all the information provided with the product at the point of sale and is not limited to the information on or attached to the package.

Nutritional supplements must be sold with the prescribed information.

There must be adequate information to facilitate investigations of adverse events or non-compliance. The contact information should reflect the arrangements in the contract and identify the person(s) responsible for the product. It must also provide a batch number, delivery reference or both so that the actual product used can be related to the manufacturing process. What is appropriate may vary for

different kinds of nutritional supplements. What is provided should be what is commonly used in the manufacture, distribution and sale for that kind of product.

There must be adequate information to allow the product to be used safely and appropriately, and before any specified expiry date.

Information on ingredients must be at least as detailed as is considered common best practice in the nutritional supplement 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. Manufacturers would be expected to provide at least that level of information.

3.3.3 Production to specifications

The nutritional supplement when offered for sale must conform to the master formulation and have been manufactured according to the manufacturing specifications.

To maintain the status of exemption from registration, manufacturers must not include any feed additive that is not listed in Part A of Schedule 7 of the Agricultural Compounds and Veterinary Medicines Regulations 2001, unless they have confirmed that the substance has been or is being recommended for inclusion in that Schedule. Some substances with therapeutic properties may fit the definition of a feed additive and be included in Schedule 7. However, inclusion in the Schedule does not justify making any therapeutic or pharmacological claims about a substance or products containing that substance. If such claims are made, the product is no longer strictly an oral nutritional preparation and may have to be registered, depending on what product group it falls into.

The records of the development of the master formulations must indicate what internationally recognised nutritional guidelines were used to ensure that use of the product as recommended would not result in either toxicity or malnutrition. Where the formulation deviates significantly from the nutritional guidelines, the records should include the technically justifiable rationale for the differences. Failure to identify the technical basis for inclusion rates and acceptable quality characteristics of ingredients will be considered as taking insufficient care to comply with the Agricultural Compound and Veterinary Medicines Regulations 2001.

It is the responsibility of the manufacturer to have reasonable checks in place and take due care to ensure that the raw materials used to manufacture the product were fit for purpose, either:

- being free of hazards; or
- subsequently processed and incorporated into the product so that they do not cause toxicity, physical damage, malnutrition, violative residues or are a source of pathogenic organisms.

Animal material used in the manufacture of nutritional supplements must comply with the requirements of the Animal Products Act 1999.

The manufacturer must document the production process, specifying actions taken during manufacture to ensure that the product met specifications and was fit for purpose. Areas of responsibility must be specified, and production systems and instructions kept current. It is expected that the manufacturing process (from specification of master formulation through packaging, labelling and dispatch) would be subject to a documented quality system, using controlled copies of the quality system or operational manual if necessary.

There must also be contingency plans in the quality system of operational manuals to recall defective product or mitigate adverse effects.

Where products in more than one product group are manufactured in the same premises, the manufacturing systems must be kept separate and secure. While GMP approval from the ACVM Group may not be required, manufacturers involved in producing different groups in the same premises should consider obtaining GMP approval from the ACVM Group to support assurances of compliance.

Manufacturers must not manufacture nutritional supplements in Groups 3, 6 or 7 unless they are registered trade name products.

Unregistered therapeutic and pharmacological substances must not be held on the manufacturing premises unless it is specified as part of the ACVM manufacturing approval. If a manufacturer holds registered PAR veterinary medicines in stock in anticipation of veterinary prescriptions, the manufacturer must either:

- be a trader registered with the ACVM Group; or
- have an authorisation from a registered veterinarian who is prepared to accept the responsibility for the overview of the storage.

To maintain the status of exemption from registration of their products, manufacturers must not stock non-GRAS substances, unregistered therapeutic or pharmacological substances or registered therapeutic or pharmacological trade name products on the premises unless those stocks are necessary for the manufacture of:

- registered products in Groups 3, 6 or 7; or
- there is an authorisation from a registered veterinarian in anticipation of particular prescriptions.

There are special concerns in regard to claims made about nutritional supplements. They must be limited to claims that can be justified in the context of a nutritional benefit (i.e. to achieve normal physiological function and metabolic homeostasis by the provision of nutrients).

Manufacturers must not intentionally include ingredients (at levels that exceed what would be reasonable to expect in the raw materials used to manufacture the product, i.e. the substances must not be supplemented) that have particular pharmacological or therapeutic activities, unless the product is registered.

4 IMPORTING ORAL NUTRITIONAL COMPOUNDS

Any oral nutritional compound imported into New Zealand must be registered unless the product complies with the conditions of exemption from registration listed in 2.2 above.

Importers are responsible for ensuring that the product and its manufacture comply with the Regulations and this standard. They must be able to show how they confirmed compliance. They must be able to confirm that the manufacturing process was equivalent to what is expected for similar products manufactured in New Zealand.

Where necessary, manufacturers must adjust the information provided with the product to meet the prescribed labelling requirements. Because there is no producer or manufacturer in New Zealand, the label must specify the importer as the person responsible for the product. The importer will be held liable if the product is found not to comply with the prescribed requirements.

5 TRADING IN ORAL NUTRITIONAL COMPOUNDS

Export-only oral nutritional compounds are not subject to this standard, Regulation 8 or Schedule 4. However, they must be identified as ‘not for sale in New Zealand’.

Products promoted, advertised and sold as oral nutritional preparations in Groups 3, 6 and 7 must be registered before they can be sold. Products in Group 4 must not be advertised or promoted in any way.

Manufacturers must ensure that oral nutritional compound products and their labelling comply with the prescribed requirements and meet this standard. Therefore, if manufacturers have met the statutory obligations, the products should be fit for purpose and be labelled appropriately.

Persons trading in such products should not alter the products in any way and must ensure that the information provided by the manufacturer is passed on to the purchaser.

If traders add any ingredients or combine different products, they will be considered to be the manufacturers of new products and will be subject to the manufacturing requirements above.

If products are altered, repackaged or relabelled by the trader, then the products are no longer the ones provided by the manufacturer. The trader must take full responsibility for any non-compliance in regard to the altered products unless the trader can show that the alterations were not the cause of the non-compliance.

Traders must not misrepresent products in any advertisement or promotion. They must not make additional claims. They must not repackage or relabel products and represent them as the original product unless they do it according to the recommendations of the relevant manufacturer.

Traders will be expected to have quality systems that maintain the identity and integrity of the products they sell, especially if they also trade in therapeutic or pharmacological products and oral nutritional preparations in Group 5. They will be expected to maintain adequate records to address any suspicions or allegations of non-compliance.

6 USING ORAL NUTRITIONAL COMPOUNDS

Oral nutritional compounds should be used as recommended. Dietary requirements and reactions to ingredients in oral nutritional preparations can vary significantly from one species to another, resulting in unnecessary pain or distress in the animals.

Products containing registered over-the-counter therapeutic or pharmacological substances should be used only as recommended. If they are used in any other manner on any other species than recommended, the user should seek veterinary advice first.

Products containing prescription animal remedy (PAR) veterinary medicines must be used only in accordance with instructions on the prescription or as specified in the label content provided as per the instructions of the prescribing veterinarian.