



Proposals for Amendment to the ACVM Regulations 2001

NZFSA Technical Amendments Discussion Paper

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Requests for further copies should be directed to:

New Zealand Food Safety Authority

P O Box 2835

WELLINGTON

Telephone : (04) 463 2500

Fax : (04) 463 2566

Website

A copy of this document can be found at www.nzfsa.govt.nz

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1 Purpose of the Paper

This paper presents proposals for amendments to the Agricultural Compounds and Veterinary Medicines Regulations 2001 (ACVM Regulations).

The Regulations exempt certain agricultural compounds, classes or groups of agricultural compounds from the requirement to be registered, therefore allowing them to be imported, sold or used without registration under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act).

Since coming into effect in July 2001, the ACVM Regulations have been amended twice, in March 2004 and May 2005. The amendments have been of a technical nature, such as removing redundant provisions and updating terminology.

The amendments proposed in this paper are of a technical nature and address issues that have arisen since the amendments to the ACVM Regulations 2001 were written, and operational issues identified during the administration of the Regulations.

2 Summary

The amendments proposed in this paper involve:

- amending the definitions of a 'fertiliser additive' and adding definitions for 'topical' and 'oral gastro-intestinal-acting microflora enhancing compound' in Regulation 3 'Interpretation';
- amending the entries in Schedule 1 for 'topical non-absorbent and non-solvent cleaning products', 'antispasmodics' and 'compounds used to protect plant grafts';
- amending the entries in Schedule 2 for 'oral and topical preparations', 'topical preparations', 'non-medicated anti-diarrhoea preparations' and 'non-medicated oral laxatives and lubricants', and adding entries to Schedule 2 for 'non-medicated poultices', 'topical hoof preparations' and 'home garden and amenity horticulture';
- adding a new exemption group for 'oral gastro-intestinal-acting microflora enhancing compounds'; and
- amending the list of substances generally recognised as safe (GRAS) under Schedule 7.

3 Amendments to Regulation 3 ‘Interpretation’

3.1 Amend the definition of ‘fertilizer additive’

It is proposed to amend the definition of a ‘fertilizer additive’ by replacing the phrase:

(a)(ii) increases biological activity in the soil; or,

with the phrase:

(a)(ii) increases biological activity; or

Comments:

The current definition of a ‘fertilizer additive’ specifies a purpose limited to increasing biological activity in the soil. However, there are trade name products that meet the definition of a fertilizer, but are not applied to soil and therefore are not captured by the current definition of a fertilizer additive. These products may contain additives that are designed to enhance biological activity in air or water, or on the plant itself. Exemption from registration is as valid for fertilizer products containing these additives as it is for those that increase biological activity in the soil.

3.2 Add definition for ‘topical’

It is proposed to add the following definition to Regulation 3:

Topical means a substance applied to the surface of the skin including the hoof, nail and hair; but not including any product intended to be administered into the eye or ear canal.

Comments:

The term ‘topical’ is included in seven exemption groups in Schedules 1 and 2 of the Regulations. The exemption is intended to apply solely to products that are applied to the surface of the skin, hair, nail or hoof. The intention was never to include products that are instilled into the ear or eye, as being covered by any exemption for topically applied products. Such products are recognised as having an

animal welfare risk profile that would be inadequately managed by non-product (group) specific assessment. Registration of such products is considered to be the appropriate risk management tool.

The proposed definition is considered necessary to make it clear that any product instilled into the ear or the eye would not be considered exempt from the registration requirement.

4 Amendments to Schedule 1

The Regulations provide a number of Schedules which list agricultural compounds that are exempt from registration under the ACVM Act 1997. An agricultural compound listed in Schedule 1 is exempt from registration if an applicable Code of Practice is complied with. This means that if there is no applicable code, then there are no conditions that must be complied with.

4.1 Amend 'Topical non-absorbent and non-solvent cleaning products'

It is proposed to clarify the intent of the sixth entry in Schedule 1 by replacing the phrase:

Topical non-absorbent and non-solvent cleaning products, including non-medicated shampoos, soaps, tear-stain removers, and toothpaste.

with the phrase:

Non-absorbed and non-solvent cleaning products, including toothpastes and topical non-medicated shampoos, soaps and tear stain removers.

Comments:

The current entry infers that cleaning products, with an absorbent action, are excluded from the exemption. However, the intent of the entry is to exclude only those products that are absorbed through the skin, as these products can be associated with residue and safety concerns.

Currently, the exemption covers toothpastes that are applied 'topically'. The general understanding of the term 'topical' is those substances that are applied to the surface of the animal, particularly to the skin, hair, nail or hoof. Toothpastes, whilst intended to clean the surface of teeth, are still applied

inside the body cavity and strictly do not meet the definition of a topically applied product (particularly in light of the proposed definition for 'topical' above).

4.2 Amend 'Antisapstains'

It is proposed to replace the 12th entry in Schedule 1 'Antisapstains' with:

Compounds used for post-harvest treatment of wood producing crops.

Comments:

This amendment would broaden the scope of the exemption from antisapstains only, to all products used during the production of wood-producing crops, from harvest to processing. There are a small number of insecticide products used post-harvest that do not fall under the current antisapstain (fungicide) exemption, but have the same risk profile. Exemption from registration is as valid for these post-harvest products as for antisapstain.

This proposal has been discussed with Biosecurity New Zealand, who have advised that the change would not jeopardise biosecurity objectives.

4.3 Amend 'Compounds used to protect plant grafts'

It is proposed to broaden the scope of the 9th entry in Schedule 1 'Compounds used to protect plant grafts' by replacing the phrase:

Compounds (not containing biologically active ingredients) used to protect plant grafts.

with the phrase:

Compounds (not containing biologically active ingredients) used to protect plant grafts and wounds.

Comments:

The current wording, which refers only to products used to protect grafting wounds, excludes some similar situations where these types of compounds are commonly used, such as thinning and pruning. In all cases, the compounds are used as a barrier to prevent dehydration and infection and have the same risk profile as those used to protect grafting wounds. This amendment will broaden the scope of the current exemption to include compounds used to protect all plant wounds, regardless of the cause of the wound.

5 Amendments to Schedule 2

An agricultural compound listed in Schedule 2 is exempt from registration if the prescribed conditions are complied with. The reader should note that the left hand column of the Schedule defines the group. The conditions that apply to the group are set out in the right hand column of the Schedule. If the compound does not fit the group, then the condition is irrelevant.

5.1 Amend 'Oral and topical preparations'

It is proposed to amend column 1 of Schedule 2 'Oral and topical preparations' by adding provision (c):

Oral and topical preparations-

- (a) prepared from either any part of a plant or an unrefined extract from a plant, except a plant listed in Schedule 6; and***
- (b) that do not claim to prevent, control or cure a specific disease characterised by pain or distress in animals; and***
- (c) that do not make pharmacological claims that imply the product may be used to prevent, control or cure a specific disease characterised by pain or distress in animals or indicate that the product has any anabolic action.***

Comments:

Currently, the only group specific characteristics that veterinary medicines must comply with to meet the definition of an 'herbal oral or topical preparation', relate to the ingredients and type of claims made to prevent, control or cure specific diseases characterised by pain and distress.

No restrictions apply to the type of pharmacological claims that can be made. As a consequence, many herbal products are marketed in association with significant claims regarding the ability of the products to modify the physiological function of an animal. Common claims include the enhancement of the function of specific body systems, which can give the impression that the product is likely to be capable of achieving the same therapeutic outcomes as registered veterinary medicines e.g. claims to enhance the production of antibodies and the activity of macrophages. Others make claims that impart anabolic actions to the product that could have a detrimental impact on trade in primary produce.

The proposed amendment will prevent unregistered herbal products being marketed in association with pharmacological claims that could result in compromised management under the ACVM Act.

5.2 Amend 'Topical preparations'

It is proposed to amalgamate Schedule 3 into column 1 of Schedule 2 'Topical preparation' and amend the wording to the following:

Topical preparations –

- (a) containing ingredients not able to be absorbed through the skin; and***
- (b) used solely to treat minor injuries or to prevent dermatological abnormalities; and***
- (c) that do not include any of the following ingredients:***
 - (1) antibiotics:***
 - (2) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981):***
 - (3) hormones:***
 - (4) substances that are prohibited by countries importing New Zealand primary produce.***

Comments:

If the wording of column 1 'Topical preparations' was amended in this manner, Schedule 3 would be redundant and could be repealed.

Schedule 2 'Oral and topical preparations' currently refers to a list of substances, included as Schedule 3, which must not be used in topical preparations. The only substances currently listed as being excluded in Schedule 3 are antibiotics. This is inconsistent with the restrictions placed on the types of substances that may be used in the treatment of own animals (see first entry of Schedule 1 ACVM Regulations 2001). Products exempt from registration via the Schedule 2 topical preparation group are eligible for general sale and therefore, have a higher distribution and use.

The exemption, under the first entry to Schedule 1, lists specific substances which may only be used if the user is operating under an ACVM approved Code of Practice that will address relevant issues, including target animal safety, residues and public health. Substances listed under the first entry to Schedule 1 are:

- (a) Active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981):
- (b) Antibiotic active ingredients:
- (c) Hormones:
- (d) Substances that are prohibited by countries importing New Zealand primary produce:
- (e) Vertebrate toxic agents.

With the exception of vertebrate toxic agents, it is considered possible that substances from each group listed above may be present in topical products.

It is legally permissible for any person in New Zealand to import, manufacture, sell or use any substance they believe is exempt from the requirement for registration without formal ACVM approval. As a result, it is considered prudent to make the types of substances that are not included in the exemption group clear.

5.3 Amend 'Non-medicated anti-diarrhoea preparations'

To prevent confusion regarding the types of products that are included in the exemption group, it is proposed to amend column 1 of Schedule 2 'Non-medicated anti-diarrhoea preparations' to the following:

Non-medicated anti-diarrhoeal preparations that -

- (a) are used solely as gastrointestinal adsorbent and/or protectant agents; and***
- (b) that do not make claims regarding the binding of any specific micro-organism or toxin.***

To reduce the likelihood of inappropriate product use, it is proposed to amend the wording of the label statement condition in column 2 of Schedule 2 'Non-medicated anti-diarrhoea preparations' to the following:

The label information must include statements that:

- (a) the product is suitable for use without veterinary advice in the treatment of minor cases of diarrhoea only; and***
- (b) that the product will not treat dehydration; and***
- (c) that if the preparation fails to alleviate the condition being treated the user should seek veterinary advice.***

Comments:

Currently there is no guidance provided with respect to what types of substances qualify as 'non-medicated anti-diarrhoea preparations'. The exemption is intended to be limited to substances with non-specific protectant and, or adsorbent actions in the gastro-intestinal tract, such as kaolin, pectins and activated charcoal. Such substances have been used as anti-diarrhoeal preparations for several decades and although diarrhoea is a disease that can be characterised by severe pain and distress, registration is unlikely to enhance the management of the risks associated with these types of products.

As a consequence of the lack of guidance, the exemption has been interpreted by some as being applicable to electrolyte replacer products, intended for use to correct the electrolyte imbalances and dehydration in animals suffering from diarrhoea. Such products are not classified as anti-diarrhoeal

preparations as they are not intended to have any effect on the symptoms of diarrhoea or the causative agent. Rather, they are therapeutic substances, intended to correct the physiologically abnormal state of the animal suffering from diarrhoea. It is critical that such animals, particularly neonates, receive products that are capable of delivering the correct quantity and ratio of electrolytes, fluid and energy. As a consequence, all electrolyte replacer products for use in the treatment of diarrhoea must be registered.

It must also be recognised that the adsorbent properties of the substances included in this exemption group are considered to be the result of their non-specific physical properties. It cannot be established with certainty that they will be capable of binding any particular organism or toxin and they may in actual fact be incapable of effectively binding some. Any claims made regarding the adsorbent properties of the products in the exemption group must be general in nature and non-specific. This will avoid creating an expectation of efficacy in the treatment of diarrhoea, resulting from any specific aetiological agent.

Although the adsorbent and protectant anti-diarrhoeal products have been in use for many years, there is a growing movement away from them as components of standard diarrhoea management programmes. Such products may result in the firming of the stool, but they do not reduce the frequency or volume, and in no way remedy the loss of fluid, electrolytes and the resultant potentially life threatening dehydration and electrolyte imbalances caused by diarrhoea.

The current exemption group specific label statement requirement is a direction to users that if the preparation fails to alleviate the condition being treated, that the user should seek veterinary advice. Over the course of several days, which is the time many animal owners would wait for a treatment response, animals can become severely dehydrated and critically ill, particularly if the diarrhoea is severe. The current label statement requirement is therefore considered inadequate to manage the risk of inappropriate product use.

5.4 Amend 'Non-medicated oral laxatives and lubricants'

It is proposed to amend the wording of column 1 of Schedule 2 'Non-medicated oral laxatives and lubricants' to the following:

Non-medicated oral and rectally administered laxative and lubricants.

Comments:

There is currently no restriction placed on the manner of lubricant use, or the mode of action. As a consequence, lubricants intended for administration via the oral, rectal and uterine routes may be considered exempt from the registration requirement.

The relevant risks, resulting from the oral and rectal administration of lubricants, are adequately managed by the current conditions of the exemption. The current manufacturing condition is considered appropriate, as there is no absolute requirement for lubricants to be sterile or unable to support microbial growth. The use of oral and rectal lubricants is largely restricted to the treatment of minor ailments, such as furballs and constipation, or to aid animal manipulations (e.g. rectal pregnancy diagnosis). The current label statement requirement, which directs users to seek veterinary advice if the preparation fails to alleviate the condition being treated, is considered adequate to manage risks.

The relevant risks, resulting from the intra-uterine administration of lubricants, are not adequately managed by the current conditions of exemption. Lubricants used in this manner are often administered in large volumes and are likely to remain in prolonged contact with an environment supportive of microbial growth. To avoid negative animal welfare outcomes, the substances used must be non-irritant and must be unable to support microbial growth. Since the formulation of these products and aspects of the manufacturing process have a direct impact on these parameters and will differ from product to product, hazard analysis and risk assessment are considered best managed via the registration process.

The current exemption does not consider laxatives that may be administered rectally. Human single dose preparations that are administered rectally and have a laxative rather than a lubricant action (e.g. Micro-Lax) are commonly used in companion animal medicine and it is conceivable that such products could be specifically marketed for veterinary use. The relevant risks resulting from the rectal administration of laxatives are adequately managed by the current conditions of exemption.

5.5 Add 'Non-medicated poultices' exemption group

It is proposed to create a new entry in Schedule 2, by adding the following exemption to column 1:

Non-medicated poultice preparations that –

(a) are used solely to provide hot or cold therapy to treat or prevent inflammation, swelling or pain or to draw out fluid from affected areas; and

(b) are intended for use on intact skin or minor wounds

It is proposed that the following conditions be included in column 2 of Schedule 2 for 'Non-medicated poultice preparations':

Must be manufactured in accordance with good manufacturing practice.

The label information must include a statement that if the preparation fails to alleviate the condition being treated, the user should seek veterinary advice.

Comments:

Poultices are a distinct group of products that are not included in the current topical product group exemptions. This is because analgesic and anti-inflammatory claims, as well as claims for drawing out pus and excessive tissue fluids, are made in relation to the temperature of the poultice and the inert hydroscopic nature of the materials used in the construction of the poultice. These claims are inconsistent with the limitations placed on the other topical product exemptions, as they can be used to treat disease states characterised by significant pain and distress.

Where claims are limited to the reduction of pain, inflammation or swelling, solely as a consequence of the heat or cold provided to the area by the poultice, or the drawing out of pus or tissue fluid as a result of the hydroscopic nature of the material, the registration requirement is considered unnecessary, as it will add nothing to the risk management of such products.

It is considered adequate to describe the physical characteristic of the types of products that will be included in the proposed exemption group as poultices, given that the common definition of a poultice is 'a soft moist mass applied to a given area'. Although it is not intended to specify what materials may be used as ingredients, poultices are generally made of substances like clay. Those products made in accordance with good manufacturing practice will be of an acceptable quality for the intended purpose.

Poultices may be considered for use on areas of intact or damaged skin. The nature of use is such that they are likely to remain in place for several hours. The use of such substances on non-minor skin wounds could potentially result in negative animal welfare outcomes and such use must be demonstrated as being safe. The safety profile will be impacted by the product ingredients and use patterns, which need to be assessed on a product by product basis. This is best achieved via the registration process.

The potential for irritation or residues resulting from any medications included in the poultice will be elevated by prolonged contact with inflamed tissue or minor wounds. Such products may compromise animal welfare or international trade and as such will be best managed on a product by product basis, via the registration process.

Although there is little objective evidence regarding the usefulness of poultices, they remain a common treatment choice, particularly for equine owners. It is considered unlikely that any animal owner would chose to use poultice preparations alone for the treatment of severe inflammation, swelling or pain. However, to reduce the likelihood that poultices would be used inappropriately or for a prolonged period of time, where inefficacy is present, it is considered necessary to include a label statement directing users to seek veterinary attention if the product fails to alleviate the condition being treated.

5.6 Add 'Topical hoof preparations' exemption group

It is proposed to create a new entry in Schedule 2, by adding the following exemption to column 1:

Topical hoof preparations-

- (a) containing ingredients with actions limited to the surface on which they are applied; and***
- (b) used solely to treat or prevent minor injuries or abnormalities of the superficial hoof; and***
- (c) that do not include any of the following ingredients:***
 - (1) active ingredients that are prescription medicines or restricted medicines (as those terms are defined in the Medicines Act 1981):***
 - (2) antibiotic active ingredients:***
 - (3) substances that are prohibited by countries importing New Zealand primary produce.***

It is proposed that the following conditions be included in column 2 for 'Topical hoof preparations':

Must be manufactured in accordance with good manufacturing practice.

Comments:

Currently there are specific exemptions in Schedule 1 for non-medicated topical hoof preparations and for non-medicated topical skin preparations. There is an additional exemption for skin preparations in Schedule 2 that may contain a medicinal ingredient; however, there is no equivalent exemption for hoof preparations.

The current topical exemption in Schedule 2 only applies to products that are not able to be absorbed through the skin. The exemption requires labelling statements that these products must be used solely for the treatment of minor injuries or to prevent dermatological abnormalities. These restrictions are necessary to prevent negative outcomes in animal welfare and trade in primary produce. Whilst these restrictions are appropriate for products applied to the skin, they are not as relevant to products applied to the hoof, where the purpose of use is to treat or prevent superficial disease. Product claims regarding the treatment of disease of the deeper structures of the hoof (e.g. white line disease, abscesses) are a concern, as there is the potential for residues to occur or animal welfare to be compromised via inefficacy or as a result of any toxic property of the product itself. In such cases, the issue is not the ability of the product to be absorbed, but its ability to penetrate the tissues or to be applied to exposed softer tissues.

There are currently no limitations placed on the type of substances that may be included in the generic group description 'topical hoof preparations'. There are however limitations placed on the equivalent exemption groups 'topical preparations' and 'substances exempted for own use'. In order to be consistent with these limitations, the relevant substances from the Schedule 1 exemption and the current Schedule 3, should be listed as specific ingredients for exclusion in the proposed exemption.

The types of products that may be exempted as part of this group are likely to contain pharmacological substances such as iodine, chlorhexidine and Stockholm tar. There is the expectation that the products will be manufactured to an adequate standard, such that the claimed degree of efficacy will be realised and negative animal welfare outcomes will not result from inappropriate manufacturing practices. A condition requiring that products be made in accordance with good manufacturing practice will alleviate such concerns.

With the restrictions placed on the type of products that may be considered exempt from the registration requirement, it is unlikely that any significant negative animal welfare outcomes will result from the failure to seek veterinary advice. It is therefore unnecessary to require any specific label warning as a condition of exemption.

5.7 Add ‘Home garden and amenity horticulture’ exemption group

It is proposed to create a new entry in Schedule 2, by adding the following exemption to column 1:

Home garden and amenity horticulture plant compounds that are used solely on non-food crops.

It is proposed that the following conditions be included in column 2 for ‘Home garden and amenity horticulture’:

The label must clearly indicate that the product must not be used on crops intended for human or animal consumption.

Comments:

Initially, the home garden and amenity horticulture contexts were considered non-agricultural as it was thought that all relevant risks were considered by the Environmental Risk Management Authority (ERMA) New Zealand. However, the potential of residues in food resulting from these situations has meant that home garden and amenity horticulture have been reclassified as “agricultural contexts”.

As there are no additional risks which would be better managed through the registration requirement, this amendment is proposed to exempt products from ACVM registration that are only used on non-food or animal feed crops.

6 Add exemption group: ‘Oral gastro-intestinal-acting microflora enhancing compounds’

It is proposed to add the following ‘Oral gastro-intestinal-acting microflora enhancing compounds’ conditions (similar to Regulation 8):

Oral gastro-intestinal-acting microflora enhancing compounds conditions

Compounds may be imported, manufactured, sold, or used as oral gastro-intestinal-acting microflora enhancing compounds without registration under section 21 or section 27 of the Act if the conditions in [new schedule] are complied with.

It is proposed to add the following definition to Regulation 3:

Oral gastro-intestinal-acting microflora enhancing compound means a substance ingested by an animal or a preparation intended for oral administration to an animal, specifically to modify the conditions of the animal's gastro-intestinal tract in-situ, to produce either a normal or favourable microflora population.

It is proposed to add the following Schedule (similar to Schedule 4) to the Regulations, stipulating specific conditions regarding oral gastro-intestinal-acting microflora enhancing compounds:

Oral gastro-intestinal-acting microflora enhancing compounds exempt from registration under sections 21 and 27 of the Act if the following conditions are complied with

1. 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 for which use is intended:***
- (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.***

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 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) result in physical harm causing pain or distress in the animal:**
 - (e) contain pathogenic micro-organisms at levels that could cause disease resulting in pain and distress in the animal.**
- 4. They must have actions limited to the maintenance or improvement of the gastro-intestinal microflora population.**
- 5. They must make no therapeutic or pharmacological claims for the treatment or prevention of any disease characterised by pain and distress.**
- 6. They must contain only ingredients that are described in Schedule 7 and used in accordance with any relevant limitations specified in that schedule.**

Comments:

Oral gastro-intestinal-acting microflora enhancing compounds are a group of substances that are increasingly being used as veterinary medicines. These products are not currently well represented by an exemption group; however, the registration requirement would not achieve increased risk management benefits compared with an exemption with conditions, for these products. These products include micro-organisms (commonly referred to as 'probiotics') and substances, such as acids/bases, that alter the environment of the gastro-intestinal tract, creating conditions that encourage the establishment of 'favourable' gastro-intestinal microflora. This can improve the ability of animals to utilise feed, or may be necessary to re-establish normal gastro-intestinal microflora following disease or treatment.

Since the ACVM Act and Regulations came into force, these substances have been considered to be feed additives and have been managed under the Schedule 4 exemption for 'oral nutritional compounds'. Any safety concerns regarding these substances have been managed via listing as Generally Recognised As Safe (GRAS) under schedule 7. This mechanism has been effective in the past, where such gastro-intestinal-modifying substances have been included as components of oral nutritional compounds. However, there is an increasing trend towards marketing such substances as stand-alone products. By definition, an oral nutritional compound is given to an animal to provide nutrients. Oral gastro-intestinal-acting microflora enhancing compounds do not fit the definition of an

oral nutritional compound, so stand-alone products can not be considered to be covered by the exemption for 'oral nutritional compounds' under Schedule 4.

This amendment clarifies the requirement and provides for the substances to be used as trade name products in their own right, ensuring that a wider range of trade name products would not attract unnecessary regulatory costs associated with registration. This can be done without increasing any relevant risks.

7 Amendments to Schedule 7

Schedule 7 manages substances which are listed as GRAS, if used in accordance with any applicable condition in Schedules 2 and 4.

It is proposed to amend the wording of the description of substances included in Schedule 7 to the following:

Substances generally regarded as safe feed additives in oral nutritional compounds and oral gastro-intestinal-acting microflora enhancing compounds.

Comments:

To accommodate the proposed new Regulation and Schedule of conditions for oral gastro-intestinal-acting microflora enhancing compounds, it is proposed to amend the description of the substances included in Schedule 7. The current use of Schedule 7 for oral nutritional compound feed additives is not proposed to change. However, as many of the substances used in oral gastro-intestinal-acting digestion enhancing compounds are already included in Schedule 7, it is considered appropriate to make the current Schedule dual purpose rather than create a dedicated register.

7.1 Proposed list of substances generally recognised as safe

See appendix for proposed GRAS list.

8 Submission Process

8.1 Guidance for Submitters

NZFSA seeks submissions from all interested parties on any aspect of the proposals presented in this document. Clear concise comments will greatly assist in ensuring that the significance of your comments is understood.

The following points may be of assistance in preparing comments:

- wherever possible, comments should be specific to a particular section of the document
- comments on other matters should be clearly stated and indicated
- comments should be to the point and, where possible, reasons and data to support comments are requested
- the use of examples to illustrate particular points is encouraged, and
- as a number of copies may be made of your comments, please use good quality type, or make sure that your comments are clearly hand written in black or blue ink.

8.2 Requirements for Submissions

Submitters are asked to include the following information in submissions:

- the title of the discussion document
- name and title of submitter
- organisation's name (if applicable)
- submitter's address and contact details (phone, fax, e-mail, if available), and
- the number(s) of the section(s) commented on beside each comment.

8.3 Official Information Act

Submissions may be the subject of requests for information under the Official Information Act 1982 (OIA). The OIA specifies that information is to be made available unless there are grounds for withholding it; such grounds are set out in the OIA. Submitters may wish to indicate grounds for withholding specific information contained in their submission, such as, that the information is commercially sensitive or personal (for example, name and contact details). Any decision to withhold information requested under the OIA is reviewable by the Ombudsman.

8.4 Closing date for Submissions

The closing date for submissions is 12 July 2006.

Please submit your response by 5.00pm on 12 July 2006 to

Chad Tustin

Policy Group

New Zealand Food Safety Authority

PO Box 2835

WELLINGTON

Alternatively, responses can be faxed to (04) 463 2583 or e-mailed to chad.tustin@nzfsa.govt.nz

8.5 Process Following Receipt of Submissions

After the closing date, submissions received will be analysed and changes made to proposals as appropriate. The amended proposals will form the basis of a paper to Cabinet requesting approval for the changes to the Regulations

9 Appendix – Amended GRAS List under Schedule 7

Substance	Identification (CAS number unless otherwise stated)	Limitations
2,4-Dichlorobenzyl alcohol	1777-82-8	To be used as a preservative only.
2-Hexenal	505-57-7	
3 –Methyl-3 –phenyl glycidic acid, ethyl ester	77-83-8	
3-hydroxy-2-methyl-4-pyrone (Palatone/Maltol)	118-71-8	Use at a level not in excess of the amount reasonably required to accomplish the intended effect
6-Methyl-5-hepten-2-one	110-93-0	
Acacia (Gum Arabic)	9000-01-5	
Acetaldehyde	75-07-0	
Acetic acid	64-19-7	
Acetoin	513-86-0	
Acetophenone	98-86-2	
Adipic acid	124-04-9	
Aldehyde C-18	104-61-0	
Allium sativum		
Allura Red	25956-17-6	
Almond shell meal		
Aloe Vera		
alpha-galactosidase		From the following sources: <i>Aspergillus niger</i> , var. <i>Mortierella vinaceae</i> , var. <i>raffinoutiliser</i> . <i>Saccharomyces</i> sp.
alpha-Pinene	80-56-8	When used at no more than 2% by weight of pesticide formulations.
Aluminium hydroxide	20768-67-6	

Ammonium chloride	12125-02-9	
Ammonium formate	540-69-2	
Ammonium hydroxide	1336-21-6	
Ammonium phosphate (mono or dibasic)	7722-76-1	
Ammonium propionate		
Ammonium sulphate	7783-20-2	
Amyl butyrate	540-18-1	
Amylase		From the following sources: Animal pancreatic tissue, <i>Aspergillus oryzae</i> , var. <i>Aspergillus niger</i> var. <i>Bacillus amyloliquefaciens</i> , <i>B. lentus</i> , <i>B. licheniformis</i> , <i>B. licheniformis</i> containing a <i>B. stearothersophilus</i> gene for alpha-amylase, <i>B. stearothersophilu</i>
Anethole	4180-23-8	
Aniseed oil	8007-70-3	
Anisole	100-66-3	
Ascorbic acid	50-81-7	
Ascorbyl palmitate	137-66-6	
Aspartame	22839-47-0	
<i>Aspergillus niger</i>		
<i>Aspergillus oryzae</i>		
Astaxanthin		
<i>Bacillus licheniformis</i>		
<i>Bacillus subtilis</i>		Non pathogenic strains
<i>Baliospermum montanum</i>		
Beeswax		
Beetroot		
Bentonite	1302-78-9	
Benzaldehyde	100-52-7	
Benzoic acid	65-85-0	≤ 0.1% of final feed
Benzyl acetate	140-11-4	

Benzyl alcohol	100-51-6	
Benzyl benzoate	120-51-4	
Benzyl paraben	94-26-8	
beta-Apo-8-carotenoic acid, ethyl ester	1109-11-1	
beta-carotene		
beta-glucanase		From the following sources: <i>Aspergillus niger</i> , var. <i>Bacillus lentius</i> , <i>B. subtilis</i> , <i>B. amyloliquefaciens</i> , var. <i>Humicola insolens</i> , <i>Trichoderma longibrachiatum</i> , <i>Penicillium funiculosum</i>
Betaine hydrochloride	590-46-5	
Bifidobacterium spp.		
Birch oil		
Boerhavia diffusa		
Brilliant Black BN	2519-30-4	
Brilliant Blue FCF	3844-45-9	
Bromolain	9001-00-7	
Bronopol		
Butyl paraben	94-26-8	
Butylated hydroxy-anisole	25013-16-5	Total content of antioxidants to be $\leq 0.02\%$ fat content of feed
Butylated hydroxy-toluene	128-37-0	Total content of antioxidants to be $\leq 0.02\%$ fat content of feed
Butylidenephthalide	551-08-6	
Butyric acid	107-92-6	
Calcium carbonate	471-34-1	
Calcium caseinate	9005-46-3	
Calcium chloride	10035-04-8	
Calcium disodium EDTA	662-33-9	
Calcium formate	544-17-2	
Calcium hydroxide	1305-62-0	
Calcium lactate	814-80-2	

Calcium lignosulfonate	8061-52-7	
Calcium methyl paraben	83542-69-2	
Calcium oxide	1305-78-8	
Calcium propionate	4057-81-4	
Calcium propyl paraben	94-18-8	
Calcium silicate	1344-95-2	
Calcium sulphate	7778-18-9	
Camphor		Maximum of 5% in premixes used in production of animal feeds.
Candida pintolepesii		
Canthaxanthin	514-78-3	
Capric [decanoic] acid	334-48-5	
Caproic acid	142-62-1	
Caprylic acid	124-07-2	
Capsanthin	465-42-9	
Capsicum Oleoresin	8023-77-6	
Caramel		
Caraway		
Carbon black	1333-86-4	
Carminic acid [cochineal]	1260-17-9	
Carmosine	3567-69-9	
Carnauba wax	8015-86-9	
Carob [locust bean]	9000-40-2	
Carophyll pink	514-78-3	
Carrageenan	9000-07-1	
Cassia gum	5373-11-5 8013-11-4	
Cayenne pepper		
Cedrus deodara		

Cellulase		From the following sources: <i>Aspergillus niger</i> , var. <i>Bacillus lentus</i> , <i>Humicola insolens</i> , <i>Trichoderma longibrachiatum</i> , <i>Trichoderma reesei</i> .
Cellulose	9004-34-6	
Charcoal, activated		
CharSol C 10	87139-45-5	
Chitosan	9012-76-4	
Chlorophyll	1406-65-1	
Chocolate brown	4553-89-3	
Choline chloride	68-48-1	
Chromium propionates		
Chymotrypsin		
Cinnamic aldehyde	104-55-2	
Cinnamon		
Citranaxanthin		
Citric acid	77-92-9	
Clove oil	8000-34-8	
Cobalt carbonate	513-79-1	
Colour Amaranth	915-67-3	
Colour Brown HT	4556-89-3	
Colour Green S	3087-16-9	
Colour Indigo Carmine / Indigotine	860-22-0	
Copper carbonate	1184-64-1	
Cryptoxanthin	465-42-9	
Curcuma domestica		
Curcuma longa		
Cyperus scariosus		Specify source
Dandelion		
Dextrose(Corn sugar)		

Di methyl polysiloxane	8050-81-5	
Diacetyl	431-03-8	
Diatomaceous earth	7631-86-9	
Dicalcium phosphate	7789-77-7	
Didecyl dimethyl ammonium bromide	2390-68-3	
Disodium EDTA	139-33-3	No more than 240mg/kg in finished feed
Disodium guanylate	5550-12-9	
Disodium Inosinate	4691-65-0	
Disodium Succinate	150-90-3	
Dolomite	16389-88-1	
Echinacea		
Elephantopus scaber		
Embelia ribes		Maximum of 5% in premixes used in production of animal feeds.
Enterococcus faecium		
Erythorbic acid	7378-23-6	
Erythrosine	16423-68-0	
Ethoxyquin	91-53-2	Maximum quantity used and to remain in feed to be $\leq 0.015\%$
Ethyl acetate	141-78-6	
Ethyl alcohol	64-17-5	Not more than 10% of the formulation
Ethyl butyrate	105-54-4	
Ethyl cellulose	9004-57-3	
Ethyl formate	109-94-4	
Ethyl heptanoate	106-30-9	
Ethyl lactate	97-64-3	
Ethyl paraben	120-47-8	
Ethyl phenylacetate	101-97-3	
Ethyl propionate	105-37-3	
Ethyl sorbate	2396-84-1	

Ethyl vanillin	121-32-4	
Ethylene diamine tetra acetic acid [EDTA]	60-00-4	
Ethyl-o-aminobenzoate		
Eugenol	97-53-0	
Fennel	8006-84-6	
Fenugreek		
Ferric chloride	7705-08-0	
Ferrous oxide	1345-25-1	
Ferrous sulphate	7720-78-7	
Food Starch and Food Starch (modified)		Use at a level not in excess of the amount reasonably required to accomplish the intended effect.
Formaldehyde	50-00-0	Less than 0.25% of final feed
Formic acid	64-18-6	
Fumaric acid	110-17-8	
Furaneol	3658-77-3	
Gamma nonalactone	104-61-0	
Gamma undecalactone	104-67-6	
Garlic	8000-78-0	
Ginger	8007-08-7	
Glucose		Includes dextrose and its hydrated and anhydrous forms
Glutamic acid	617-65-2	
Glycerides (mono and di)		
Glycerine	56-81-5	
Glycerol	56-81-5	
Glycerol mono-oleate	25496-72-4	
Glycerol monostearate	31566-31-1	
Glycerol polyethyleneglycolricinoleate E484 (Bredol 683)		

Glycerol triacetate	102-76-1	
Guar gum	9000-30-0	
Gypsum	10101-41-4 3397-24-5	
Haematococcus algae		
Hemicellulase		From the following sources: <i>Aspergillus niger</i> , var. <i>A. aculeatus</i> , <i>Bacillus lentus</i> , <i>B. subtilis</i> , var. <i>Humicola insolens</i> , <i>Trichoderma longibrachiatum</i>
Holarrhena antidysenterica		
Hydrogenated Palm Stearine	11099-07-3	
Hydroxypropyl cellulose	9004-64-2	
i-carrageenan	9062-07-1	
Inulin	9005-80-5	
Iron oxides - black	1317-61-9	
Iron oxides – red	1309-37-1	
Iron oxides – yellow	51274-00-1	
Isoamyl Acetate	123-92-2	
Isoamyl Isovalerate	659-70-1	Not to exceed 1ppm in final feed
Iso-eugenol	97-54-1	
Isopropyl alcohol	67-63-0	
Kaolin	1332-58-7	
k-carrageenan	11114-20-8	
Kombu Seaweed		
Konjac gum	9000-36-6	
Lactic acid	50-21-5	
Lactobacillus acidophilus		
Lactobacillus bifidus		
Lactobacillus bulgaricus		
Lactobacillus casei	68333-14-2	

Lactobacillus delbrueckii subspecies lactis		
Lactobacillus fermentum		
Lactobacillus plantarum		
Lactobacillus rhamnosus		
Lactose	63-42-3	
Lauric acid	143-07-7	
l-carrageenan	9064-57-7	
Lecithin	8002-43-5	
Lemon grass		
Lemon oil	8008-56-8	
Licorice (Glycyrrhiza)		Includes all licorice derivatives. Not more than 0.1% in final feed.
Lignosulphonates		
Lime oil	8008-26-2	
Limonene	138-86-3	
Linalool	78-70-6	
Lipase	9001-62-1	From the following sources: Animal pancreatic tissue, aspergillus niger, var. A. oryzae, var. Candida rugosa, Rhizopus sp, edible forestomach of calves, kids and lambs.
Locust bean gum	9000-40-2	
Lutein	57-83-0	
Lycopene	502-65-8	
Macrogol esters (polyethylene esters)	9000-99-3	
Magnesium acetate	142-72-3	Includes hydrated forms. Only added to the levels needed.
Magnesium aluminium silicate	1327-43-1	Includes hydrated forms. Only added to the levels needed.
Magnesium aspartate	18962-61-3	Includes hydrated forms. Only added to the levels needed.
Magnesium carbonate	546-93-0	Includes hydrated forms. Only added to the levels needed.

Magnesium chloride	7791-18-6	Includes hydrated forms. Only added to the levels needed.
Magnesium citrate	3344-18-1	Includes hydrated forms. Only added to the levels needed.
Magnesium gluconate	3632-91-5	Includes hydrated forms. Only added to the levels needed.
Magnesium glutamate	64407-99-4	Includes hydrated forms. Only added to the levels needed.
Magnesium glutamate, D,L	64407-99-4	Includes hydrated forms. Only added to the levels needed.
Magnesium glycerophosphate	927-20-8	Includes hydrated forms. Only added to the levels needed.
Magnesium hydroxide	12141-11-6	Includes hydrated forms. Only added to the levels needed.
Magnesium hypophosphite		Includes hydrated forms. Only added to the levels needed.
Magnesium orotate	34717-03-8	Includes hydrated forms. Only added to the levels needed.
Magnesium oxide	1309-48-4	Includes hydrated forms. Only added to the levels needed.
Magnesium phosphate	10043-83-1	Includes hydrated forms. Only added to the levels needed.
Magnesium silicate	1343-88-0	Includes hydrated forms. Only added to the levels needed.
Magnesium stearate	557-04-0	Includes hydrated forms. Only added to the levels needed.
Magnesium sulphate	7487-88-9	Includes hydrated forms. Only added to the levels needed.
Magnesium trisilicate	14987-04-3	Includes hydrated forms. Only added to the levels needed.
Malic acid	6915-15-7	
Maltodextrin	9050-36-6	
Maltol	118-71-8	
Mannan endo-1,4-beta-mannosidase	37288-54-3	From the following sources: <i>Aspergillus niger</i> , var. <i>Bacillus lentus</i> . <i>Trichoderma Longibrachiatum</i> . For use in Poultry feed only.
Mannitol	87-78-5	

Marigold, Aztec		
Menthol		Not for use in cats
Metalloproteinase		From Bascillus Subtilis var.
Methyl alcohol	67-56-1	
Methyl paraben	99-76-3	
Methyl salicylate	119-36-8	
Mineral oil		High viscosity
Mineral oil	8012-95-1	Medium and Low Viscosity. Not to exceed 0.06% of final feed.
Monoisopropyl citrate	1321-57-9	
Monopotassium phosphate	7778-77-0	
Monosodium glutamate	32221-81-1	
Myrica nagi [bayberry]		
Neohesperidine dihydrochalcone	20702-77-6	When used at no more than 30ppm in finished feed
Neotame	165450-17-9	
Nonyl Phenol Ethoxylate	9016-45-9 26027-38-3	
Octyl gallate	1034-01-1	
Onion oil	2179-59-1	
Operculina turpethum		
Orange oil	8008-57-9	
Oregano		
Pancreatin		
p-Anisaldehyde	123-11-5	
Papain	9001-73-4	
Paprika		
Para-formaldehyde	30525-89-4	See formaldehyde
Patent Blue V	129-17-9 3536-49-0	

Pectinase	9032-75-1	
Pediococcus acidilactici		
Pediococcus pentosaceus		
Peppermint oil		Not for use in cats
Pericol black	2519-30-4	
Phenylacetic acid	103-82-2	
Phosphoric acid	7664-38-2	
Phyllanthus emblica		
Phytase		From the following sources: Aspergillus niger, var. A. oryzae, var. Schizosaccharomyces pombe
Picrorhiza kurroa		
Piper longum		
Piper nigrum		
Piper officinarum		
Pistacia integerrima		
Plumbago zeylanica		
Polyethylene oxide, polypropylene glycol block copolymer	9003-11-6	
Polyoxethylene nonyl phenyl ester	9016-45-9	Only to be used as a wetting agent. Not more than 0.5% of formulated product.
Polyoxyethylene (20) sorbitan monolaurate	9005-64-5	
Polyoxyethylene (20) sorbitan monooleate	9005-65-6	
Polyoxyl 35 Castor Oil (Cremphor EL)		
Polyoxyl 40 Castor Oil (Cremphor RH 40)		
Polyoxyl 60 Castor Oil (Cremphor RH 60)		
Polyvinylpyrrolidone	9003-39-8	
Ponceau 4R	2611-82-7	When used at no more than 50mg/kg in finished feed.

Potassium carbonate	584-08-7	
Potassium chloride	7447-40-7	
Potassium hydroxide	1310-58-3	
Potassium lactate	85895-78-9 996-31-6	
Potassium sorbate	590-00-1	
Potassium/sodium lactate mixture		
Propionic acid	79-09-4	
Propyl acetate	109-60-4	
Propyl alcohol	71-23-8	Not more than 55g/head/day
Propyl benzoate	2315-68-6	
Propyl gallate	121-79-9	Total content of antioxidants to be $\leq 0.02\%$ fat content of feed
Propyl paraben	94-13-3	
Propylene glycol	57-55-6	
Protease		From the following sources: <i>Aspergillus niger</i> , var. <i>A. oryzae</i> , var. <i>Bacillus amyloliquefaciens</i> , <i>B. licheniformis</i> , <i>B. subtilis</i> , var. <i>B. subtilis</i> , containing a <i>B. amyloliquefaciens</i> gene for protease, <i>Rhizopus</i> Sp.
Pumice		
Raffinase		
Rapeseed oil	8002-13-9	Includes Hydrated Forms.
Rennet		
Rosemary	8000-25-7	
Rosemary oleoresin		
Rum ether	8030-89-5	
Rutin	153-18-4	
Saccharin sodium	128-44-9	
<i>Saccharomyces cerevisiae</i>		
Sage oil		

Saponified marigold extract		
Saponified paprika extract		
Silica (silicon dioxide)	7631-86-9	
Silicone antifoam	63148-62-9	
Skatole	83-34-1	
Sodium acid pyrophosphate		
Sodium alginate	9005-38-3	
Sodium alkyl benzene sulphonate	25155-30-0	Not to exceed 0.2% in solution
Sodium aluminosilicate	73987-94-7	
Sodium ascorbate	134-03-2	
Sodium benzoate	532-32-1	≤ 0.1% of final feed
Sodium bicarbonate	144-55-8	
Sodium butyl paraben	40167-95-1	
Sodium carbonate	497-19-8	
Sodium carboxy methylcellulose	9004-32-4	
Sodium chloride	7647-14-5	
Sodium citrate	68-04-2	
Sodium cyclamate	139-05-9	
Sodium erythorbate	6381-77-7	
Sodium formate	141-53-7	
Sodium fumarate	7704-73-6	
Sodium hexametaphosphate	10124-56-8	
Sodium hydroxide	1310-73-2	≤ 0.5% of final feed
Sodium lignosulphonate	8061-51-6	
Sodium metabisulphite	7681-57-4	
Sodium methyl paraben	5026-62-0	
Sodium nitrite	7632-00-0	≤ 1% of final feed
Sodium propionate	137-40-6	

Sodium propyl paraben	35285-69-9	
Sodium silico aluminate	1344-00-9	< 2% of final feed
Sodium thiosulfate	7772-98-7	
Sodium tripolyphosphate	7758-29-4	
Sorbic acid	110-44-1	
Sorbitan fatty acid esters (fatty acids limited to C12, C14, C16 and C18 containing minor amounts of associated fatty acids) and poly(oxyethylene) derivatives of sorbitan fatty acid esters		
Sorbitan monooleate	1338-43-8	
Sorbitan monostearate	1338-41-6	
Sorbitol	50-70-4	
Streptococcus (Enterococcus) salivarius subspecies thermophilus		
Sulphamic acid	5329-14-6	
Sulphuric acid	7664-93-9	
Sunflower oil	8001-21-6	
Sunset yellow	2783-94-0	
Tagetes oil	8016-84-0	
Tangerine oil	8008-31-9	
Tartaric acid	87-69-4	
Tartrazine	1934-21-0	
Terminalia belerica		
Terminalia chebula		
Tertiary butylhydroquinone (TBHQ)	1984-33-0	
Tetra potassium pyrophosphate	7758-87-4	
Tetra sodium pyrophosphate	7722-88-5	
Thaumatococin	53850-34-3	
Thyme oil	8007-46-3	

Thymol	89-83-8	When added at levels consistent with good feeding practice
Titanium dioxide	13463-67-7	
Tocopherols (extracts of natural origin)	1406-66-2	
Tricalcium phosphate	7758-87-4	
Trimethylamine	75-50-3	
Trisodium Phosphate	7601-54-9	
Trypsin		
Turmeric	8024-37-1	
Undecylenic alcohol	112-43-6	
Urea	57-13-6	
Valerian		
Valeric acid	109-52-4	
Vanillin	121-33-5	
Vermiculite	1318-00-9	
Vitamin B1		
Vitamin B12		
Xanthan Gum	11138-66-2	
Xanthophyll	127-40-2	
Xylanase	9025-57-4	From <i>Aspergillus oryzae</i> carrying a gene from <i>Thermomyces lanuginosus</i> coding for xylanase or from <i>Penicillium funiculosum</i> or <i>Trichoderma longbrachiatum</i> or <i>Trichoderma viride</i> .
<i>Yucca schidigera</i>		
Zeaxanthin		
Zinc oxide	1314-13-2	
Zinc propionates		
<i>Zingiber officinale</i>		