



**Transfer of  
Substances**

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY  
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



# **Summary of Submissions: Group Standards for Animal Nutritional Products**

March 2006

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# 1. Introduction

## 1.1 Background to the Consultation

This document reports on the submissions that were received on proposals to establish group standards for animal nutritional products. Group standards are a form of hazardous substances approval under Part 6A of the Hazardous Substance and New Organisms (HSNO) Act 1996.

ERMA New Zealand released for public consultation two group standards for animal nutritional products on 31 October 2005. Consultation closed on 12 December 2005. Notification of this consultation was via public notice in the four main metropolitan newspapers and the ERMA New Zealand web site.

The consultation document and draft group standards,<sup>1</sup> or a letter advising of the availability of these documents, were provided to approximately 350 parties who were considered likely to have an interest in this consultation. This included companies who notified animal nutritional or related products under the Toxic Substances Act 1979, other industry sectors and associations, government departments, enforcement agencies and territorial authorities. The documentation was also available on the 'consultation page' of the ERMA New Zealand website.<sup>2</sup>

Sixteen submissions were received, with none of the submitters requesting a hearing.

The comments made by submitters are summarised in Section 2, along with the Agency's response. Where a submitter's comment resulted in a change to the group standard proposal, this is indicated in the table. Each submitter is identified numerically, and the name of the submitter given after the table.

The following commonly occurring points were made in the submissions:<sup>3</sup>

- Certain notified products (NOTS) were placed in the wrong group standard and it was requested that they be moved to the correct group standard (see Section 1.2);
- Clarification around labelling and safety data sheets, particularly a concern that some conditions were not consistent with the hazardous substances regulations;
- Concern that these products are being over regulated, as they are very low risk and no previous problems have been experienced.

This summary of submissions has been provided to all parties who made a submission on the animal nutritional product group standard proposals, all notifiers of animal nutritional products (whether or not they made a submission) and to the Hearings Committee of the Authority.<sup>4</sup> It is also available from the ERMA New Zealand web site: <http://www.ermanz.govt.nz/consultations/gs/anp.asp>. A copy will be provided to any other interested party on request.

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<sup>1</sup> Provided electronically on CD. No paper copies were distributed unless specifically requested.

<sup>2</sup> These documents remain available on the ERMA New Zealand web site: <http://www.ermanz.govt.nz/consultations/gs/anp.asp>.

<sup>3</sup> These themes were also common to group standard proposals for other application types.

<sup>4</sup> The Authority is the decision making body of ERMA New Zealand. It is made up of up to eight members appointed by the Minister for the Environment. The Hearings Committee is made up of selected members of the Authority with relevant experience in the subject area being considered for approval under the HSNO Act.

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## 1.2 Moving NOTS

Where a submitter requested that a NOTS be moved from one group standard to another, this information is not provided in Section 2, because it is specific to that notifier and in some cases could result in the disclosure of confidential information. This moving of NOTS is independent of the scope and conditions of a group standard, and consequently has not resulted in any change to any of the group standard proposals.

To assist notifiers reassign their NOTS, ERMA New Zealand has developed an excel template that can be accessed by emailing us at: [NOTS@ermanız.govt.nz](mailto:NOTS@ermanız.govt.nz).<sup>5</sup> Once the notifier has recorded on the template the NOTS that need to be moved, they must email the completed template back to us for processing. This template will be available up until 30 June 2006.

Where notifiers requested as part of their submission that NOTS be reassigned, we will move them to the group standard(s) they indicated, and they do not need to use the template unless they have further changes to make.

## 1.3 Overlap of Consultation with Chemicals of Concern

The group standard proposals included a condition requiring notification to the Authority if a substance contains a Chemical of Concern. A separate consultation on the concept of developing a list of chemicals of concern was undertaken concurrently with the group standards consultation. Submissions received on the chemicals of concern provision of group standards are included in the summary of submissions from the Chemicals of Concern consultation. Copies of this summary of submissions will be provided to all submitters on the group standards.

## 1.4 Combining Group Standards

As group standards have been finalised following consultation, we have found it advantageous to combine or “roll-up” certain group standards by:

1. application type, and/or
2. hazard.

The two group standards; animal nutritional products (low hazard) and animal nutritional products (medium hazard) have been combined into a single group standard, and renamed as *Animal Nutritional and Animal Care Products Group*

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<sup>5</sup> The template and process operate in such a way that requires notifiers to contact ERMA New Zealand. This is to safeguard data confidentiality.

*Standard.* Animal care products have been combined with the nutritional products as they have a similar use (i.e. animal care and wellbeing, although they are used externally rather than internally) and similar hazards.

From the consultation on other sets of group standards, submissions were received requesting that group standards be combined to reduce the number industry would otherwise have to deal with. A preference for fewer group standards was confirmed in separate discussions with a number of industry sectors. We also recognised the advantages of rolling up group standards from a management and administrative perspective, provided that, in so doing, the combined group standards were no less user-friendly or the conditions more onerous to comply with.

The rolling-up of group standards has been possible because of the template format on which they are based. Importantly, combining group standards has not meant that there are further requirements on a substance approved under that combined group standard than would have applied if the individual group standards were kept separate. It does, however, mean that, for some conditions, various options are presented, and the relevant option has to be selected depending on the hazard of the substance concerned.

Parties who read the original group standard proposals will also notice that the group standards have been reformatted to simplify the numbering scheme and to improve their readability and presentation. In addition, some editing and word-smithing has been carried out. Again, this reformatting and editing has not changed the requirements of any aspect of the group standard.

## **1.5 Approval of Group Standards**

The Hearings Committee of the Authority is responsible for considering and approving group standards. Copies of amended group standards will be provided to the Committee for consideration.<sup>6</sup>

As noted earlier, a copy of this summary of submissions has been provided to the Hearings Committee. Although Section 2 of this summary may indicate that an amendment has been made to the group standards as consulted on, it is the Hearings Committee that is the decision maker. That is, the Agency's recommendation that a group standard be changed as indicated in Section 2 requires final approval by the Authority.

The Hearings Committee is scheduled to consider the group standard for *Animal Nutrition and Animal Care Products* on 22 March 2006. A notice of their decision will be placed on the ERMA New Zealand web site as soon as practicable after the consideration.

Because we have identified a need to undertake further consultation on key matters concerning group standard proposals, any decision of the Hearings Committee will only be an interim (provisional) decision at this time (see following section).

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<sup>6</sup> Group standards that were consulted on will be amended as indicated in Section 2.

## **1.6 Further Consultation Required**

Since the release of the original group standard proposals, there is a need for further consultation to:

1. address matters inadvertently omitted from some group standards, particularly with respect to tracking of the most toxic (Classes 6.1A and 6.1B) substances and the labelling of hazardous ingredients; and
2. seek further feedback on certain points raised by submitters from the initial consultation.

A copy of this consultation document will be available in late March 2006 from <http://www.ermanz.govt.nz/consultations/consult-gs.asp>.

As a consequence of undertaking further consultation, there will be a further consideration by the Hearings Committee to address these additional matters and give final approval to the group standards proposed. This consideration is scheduled for June 2006.

## **1.7 Gazetting of Group Standards and Staged Implementation**

Following final approval by the Authority, group standards will be established by publication of a notice in the *New Zealand Gazette*, and will come into force on 1 July 2006. All NOTS that fit the scope of a group standard will become deemed approved hazardous substances at this time.

Coinciding with the transfer of NOTS will be the commencement of a period of staged implementation. The details of staged implementation are given in Annex 1.

After 1 July 2006, ERMA New Zealand will write to all notifiers with a list of their NOTS that are deemed approved under group standards and the HSNO approval number for each group standard.

## 2. Submitter's Comments and Agency Response and Recommendation

Submitter	Submission comment	Agency response and recommendation	Group standards amended
<b>General comments on the group standards</b>			
3	We appreciate the efficiencies that Group Standards offer and see the animal nutritional product groupings as an appropriate way to transfer them into HSNO.	Support noted	No amendment required
5	<p>The proposed Group Standards are inappropriate for these low risk substances. I find it incongruous that nutritional products that meet the NZFSA food safety criteria are now classified as Notified Toxic Substances.</p> <p>A more non-regulatory approach is required – low risk products should not require Group Standards. People are perfectly safe at the concentrations and exposure that occur in real life. The NZFSA requirements are adequate and have served the industry without mishap for years. Many products are foil sealed and do not require contact with the contents.</p> <p>All that is necessary is a generic statement informing users of the risks.</p>	<p>The HSNO framework is designed to manage substances that exhibit hazardous properties above certain thresholds. Group standards are one means by which notified products (NOTS) can be transferred from the transitional provisions to the main framework of the HSNO Act.</p> <p>If products do not exceed the threshold criteria, then they are not captured by the group standards and none of the conditions apply. Notifiers have the ability to determine that a product is non-hazardous under HSNO and remove it from a group standard. This is explained in the consultation document.</p> <p>If a substance triggers any one of the HSNO thresholds, then the conditions are set out in the group standard, and include basic labelling provisions, protective clothing, and packaging. Packages less than certain specified quantities are exempt from some of the labelling and packaging requirements.</p> <p>Because the NZSFA criteria are met does not mean that a product is non-hazardous. HSNO and the ACVM Act are designed to manage different sets of risks, and consequently both sets of regulatory requirements must be considered in tandem.</p>	No
6	We support the concept of Group Standards to streamline the transfer of NOTS to the HSNO Act. It is imperative that information is expressed in a more direct user-friendly way than the regulations. We agree they are a more efficient and effective way of managing the risks of a group of substances than individual HSNO approvals.	Support noted	No amendment required
6	We recommend that ERMA investigate Group Standards for parasiticides and for other veterinary	Veterinary medicines were transferred individually to the main HSNO framework on 1 July 2005. At this point in time, ERMA New Zealand's	No amendment required

Submitter	Submission comment	Agency response and recommendation	Group standards amended
	medicines.	priority is the transfer of NOTS that are still covered by the transitional provisions. Currently, ERMA New Zealand is unlikely to initiate group standards for already transferred veterinary medicines (such as parasiticides). However, this initiative could come independently from industry via an application to ERMA New Zealand.	
9	We have interests across a wide range of industries and we would like to provide further comment on these Group Standards once other matters in discussion with ERMA have been resolved.	Noted. Further discussions have occurred with this submitter, which has led to clarification and proposed changes to labelling. Also as a result of these discussions, further consultation on matters, including child resistant packaging, will be undertaken.	Yes – to conditions for labelling
11	I support Group Standards in general as a means of transfer.	Support noted	No amendment required
12	We generally support the controls specified and agree they are more user friendly than the regulations.	Support noted	No amendment required
<b>Definitions</b>			
3	We believe the definition of substances covered in these group standards is appropriate.	Comment noted. An explanatory note will be included in the group standard to clarify a matter raised by submitter 6 (see below).	Explanatory note to be included.
6	We are concerned that the definitions for animal nutritional product and nutritional benefit are ambiguous and should be reworded for clarification. Suggested wordings are: 1. <b>Animal Nutritional Product</b> means a commercially manufactured and packaged non-nutrient substance intended for administration to an animal to achieve a nutritional benefit in addition to the normal physiological function achieved by provision of nutrients.” 2. <b>Nutritional benefit</b> means a contribution to the normal physiological function and metabolic homeostasis of an animal achieved by the provision of nutrients.” 3. 4.1(1) Substances covered by this Group Standard are non-nutrient substances which are imported or manufactured and commercially packages for administration to an animal to	The definitions are appropriate for the types of minerals and nutrient materials covered by this group standard. Further discussions have taken place with this submitter. An explanatory note will be included to clarify that silage, hay, grain and other grown feedstuffs that are otherwise unadulterated with supplementary minerals or other components fall outside the scope of the group standard.	No amendment required to definitions, but an explanatory note will be included.

Submitter	Submission comment	Agency response and recommendation	Group standards amended
	<p>achieve a nutritional benefit in addition of the normal physiological function achieved by provision of nutrients.”</p> <p>4. <b>Nutrient</b> means 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.</p>		
<b>Classification and the allocation of NOTS to group standards</b>			
1	Our products are oral nutritional supplements and are not toxic substances. These products are not hazardous and should not be in these Group Standards. Included is a class determination by ACVM to show this.	The ACVM class determination is not equivalent to a substance being non hazardous under HSNO. HSNO and the ACVM Act are designed to manage different sets of risks, and consequently these regulatory requirements must be considered in tandem.	No amendment required
2	We dispute the class 9 classification as the substance is an insoluble solid. LC50s in the attached SIDS report are above 100 mg/L and thus above the threshold. We also note that none of the toxicity thresholds are triggered by this product.	The classification assigned to substances is a 'guide' based on the information provided by industry to ERMA New Zealand at the time of notification or available to us from the ACVM. No comprehensive hazard assessment has been undertaken. As explained in the consultation document, the industry is able to reassess the hazardous of their products, and based on their self-classification follow the conditions of the group standard that are relevant for that classification. If industry has product specific data then that should be used in determining the hazard classification. Such data was not always provided to ERMA New Zealand.	
8	We would like our product reallocated to the low risk group standard as it has similar concentrations of specified elements to other products in that group standard.	The low hazard and medium hazard group standards have been combined into a single group standard. The low hazard standard was simply a subset of the medium hazard, and “combining” these standards avoids unnecessary duplication. This is explained further in Section 1.4.	
11	It appears that products have been allocated to Group Standards on a somewhat arbitrary basis. I propose that companies be able to make a case for reallocation of their products.	<p>Products were allocated to group standards on the basis of compositional information and the hazard properties of those components. Companies provided the compositional data at the time of notification, although this was not comprehensive in all cases. Information was also sourced from the ACVM.</p> <p>The consultation document noted that where ERMA New Zealand has assigned a product to the incorrect group standard, then the notifier is</p>	No amendment required

Submitter	Submission comment	Agency response and recommendation	Group standards amended
		<p>able to reassign it to a different group standard. We asked that where this reassigning was carried out, companies advise us so we would be assured that all NOTS were transferred. We have since developed an excel based tool for companies to reassign their NOTS to a different group standard. This is available by emailing us at <a href="mailto:NOTS@ermanz.govt.nz">NOTS@ermanz.govt.nz</a>.</p> <p>Note that because of the rolling up of group standards (see Section 1.4), there is now only one group standard for animal nutritional products.</p>	
11	<p>The thresholds appear to be too low in relation to the risks involved with such products. These products have been around for years with very few problems associated with widespread use. Unnecessary regulation only adds to the complexity and expense of products.</p>	<p>The hazardous property thresholds are set out in the HSNO regulations. These thresholds are adopted from the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) see <a href="http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html">http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html</a></p> <p>The group standards have adopted these same thresholds and applied them to groups of similar substances.</p> <p>ERMA New Zealand is committed to the adoption of GHS.</p>	No
13	<p>Our product should not have a classification of 6.1D and thus should not be in the medium risk group standard.</p>	<p>This submitter was responded to individually explaining the basis of the classification given and why the product was assigned to the medium hazard group standard.</p>	No amendment required
14	<p>Self classifying is challenging to many companies. Many do not realise how low the thresholds are. It will prove costly for label amendments.</p>	<p>ERMA New Zealand is aware of the need to provide relevant information and tools to support the classification of substances by industry. The premise of the HSNO Act is industry self-management. Consequently, group standards are based on industry being able to assign their products to the appropriate group standard, and the necessary guidance and processes must be in place for this to occur.</p>	No amendment required
15	<p>There is a concern that these Group Standards will not manage the risk to the environment as there is no way of monitoring which substances companies deem to be covered by these group standards. As their knowledge about the safety and toxicity of their products is often not good we recommend that companies be able to submit their classifications to ERMA for confirmation to give the industry confidence they are complying correctly.</p>	<p>The provision of information and supporting tools will be a priority once group standards come into force and during the implementation period.</p> <p>For companies who would prefer not to self-classify or who wish to get some confirmation from ERMA New Zealand of their self-classification and labelling requirements, we will be offering a product classification service. This will be similar to the SOS process currently provided by ERMA New Zealand.</p> <p>For a company that self-classifies its products, the issue of whether they place those products in the correct group standard is one of compliance and enforcement. We are currently reviewing whether there are options for the auditing of group standards to ensure a high level of compliance.</p>	

Submitter	Submission comment	Agency response and recommendation	Group standards amended
<b>Conditions for packaging</b>			
2	99.9% of our products are manufactured and packaged overseas. We have a concern that our products in this group standard are required to comply with Packing Group 3 although they are not classified as UN PG III. It is not feasible or practical for us to repackage them.	The hazards triggering packaging group requirements have been amended to align directly with the provisions of the UN Transport of Dangerous Goods Model Regulations (UN TDG). For example, an irritancy hazard no longer triggers a PG3 requirement. If your product is currently not classified and transported as UN PG3, then similarly compliance to PG3 should not be required under the group standard.  That aside, with group standard staged implementation, compliance with the packing conditions will not be required till 1 July 2008.	Yes – align PG triggers with the UN TDG
7	Our product is packaged in a plastic injection vial, which is not breakable. The closure is a tamper proof cap. The rubber bung (through which an injection needle is pushed to withdraw the contents) is sealed with a metal cap. Thus the product is child resistant. We wish our product to be reallocated to the low risk group standard.	A product is assigned to a group standard on the basis of its hazard, which triggers the packaging requirement for that product. The issue is whether the packaging meets the requirements of the group standard. The nature of the packaging you describe with a tamper proof cap is likely to meet the child resistant packaging requirement of the group standard, meaning that, at least in this regard, you are already compliant with the requirements of the group standard.	No amendment required
10	For low risk products surely a simple “Dispose of spillage and packaging in landfill or by incineration” should be adequate.	This statement would comply with the group standard condition that requires the provision of disposal information on a product label.	No amendment required
<b>Conditions for labelling</b>			
3	Labelling should be consistent with the ACVM Act and include the words “For animal treatment only” as is already required by the ACVM Act. WE recommend that ERMA staff discuss labelling with the ACVM group.	Agreed. The wording will be changed to “For Animal treatment only”, and will apply only to products that are applied or administered to an animal.	Yes – amendment to wording as proposed
4	To harmonise the label wording with ACVM requirements by adding “For animal treatment only”.		
4	The hazard statement for 6.1E in section 5.1.2.2(2)(a) is not consistent with the regulations.	Incorrect. This condition requires a label statement “keep out of reach of children” where a substance is available to the general public. It is not required in a place of work where it will not be available to the public. Compare, the HSNO ID regulations, which requires information “indicating the need to restrict access by children” for a 6.1 substance (including a 6.1E substance) that is intended to be sold to members of the public.	No

Submitter	Submission comment	Agency response and recommendation	Group standards amended
5	To place a 24 hour emergency number on a label of rabbit premix is not only unrealistic for small companies to comply with, but for what purpose, on products already classified as low risk?	This condition is based on the HSNO regulations, but has been made more stringent in a number of aspects. The condition will be amended to align with the current regulatory requirements. The need for a 24 hour emergency phone number is a requirement of the Emergency Management Regulations for certain hazard classifications.	Yes – amend the 24-hour requirement to align with HSNO regs.
10	These products are low risk and inherently safe and such things as pictograms and 24 hour emergency numbers are overkill.	An alternative compliance measure has been included, which will allow for compliance with the labelling requirements of the group standard via compliance with the HSNO Identification, Emergency Management and Packaging regulations.	New condition included to provide for an alternative means of compliance
12	We are pleased with the prescriptive statements required on the label in these Group Standards including the address details as this is useful for enforcement. Will it be required for substances other than Group Standards?	<p>Support noted for prescriptive label statements.</p> <p>Regarding company contact details, a number of submitters on these and other group standards have pointed out that the requirement for an address and phone number were more onerous than those set out in the HSNO Identification and Emergency Management regulations. This was not the intention at the time this group standard clause was drafted. The wording in the group standards will be amended to align directly with those of the regulations.</p> <p>For substances that already have HSNO approvals by means other than group standards (e.g. Part V approval, or a transfer under s160A of the Act), the regulations will continue to apply and not the prescriptive statements given in the document <i>Hazard and Precautionary Information for Group Standards</i>. However, companies may decide to use these statements as a means of compliance with the regulations.</p>	<p>No – for any change to the prescriptive nature of the label statements</p> <p>Yes – for contact details</p>
14	Our members are aware of their responsibilities under HSNO but there are other companies that are not and by not upgrading their labelling etc put our members at a commercial disadvantage. ERMA needs to reach out to these companies as well.	<p>ERMA New Zealand will be disseminating information on the establishment and compliance requirements of group standards. Work in this area has already commenced, and will continue after 1 July 2006, when group standards come into force.</p> <p>Commencing on 1 July will be a period of staged implementation to give companies time to become familiar and fully compliant with the requirements of the group standards, including the labelling provisions. The details of staged implementation are set out in Annex 1 of this document. Once this staged implementation period expires, if a company is non compliant with the group standard conditions then this is an enforcement issue for the relevant HSNO enforcement agency. There is nothing to prevent a company advising an enforcement agency of instances of non-compliance.</p>	No amendment required

Submitter	Submission comment	Agency response and recommendation	Group standards amended
16	<p>These group standards appear to take away some of the discretion in labelling allowed in the regulations. <i>We would like the discretion to use the AGCARM labelling guide as an alternative means of compliance with this group standard.</i></p> <p>We are concerned that the product labelling required in this group standard will make the products look very dangerous, particularly statements such as “Suspected of causing genetic defects” which will cause concern for farmers with pregnant stock.</p> <p>Also statements referring to respiratory problems and breathing are irrelevant as this is a granular product. We are also concerned about the requirements of pictograms for chronic toxicity. We are unsure of what discretion is allowed to use or not use or vary these statements.</p>	<p>The labelling provisions of the group standards allow for a number of alternative means of compliance, including the HSNO Identification regulations, and compliance with a code of practice approved by the Authority, if that code specifies requirements equivalent to those set out in the labelling conditions.</p> <p>The AGCARM code of practice (which has been submitted to ERMA New Zealand for approval) will be able to be used as a means of compliance with the relevant labelling requirements of the group standards.</p>	No
16	<p>These products are applied to pasture to correct mineral deficiencies in soil and thus stock. The statement “For Animal Use Only” is not relevant for an animal nutritional product applied to pasture.</p>	<p>The group standard will be amended to make it clear that this statement (which as noted above is being re-worded to align with the comparable ACVM provision) will only apply to products that are applied or administered to an animal.</p>	Yes
16	<p>There seem to be a number of inconsistencies with the regulations and the AGCARM labelling guide for 9.1C, 9.2C and 9.3C.</p> <p>A 6.1 substance (other than 6.1E) requires the statement “Keep out of reach of children”. This should apply to these products as they are 6.1D but this is not required in the group standard.</p>	<p>The AGCARM code (which has been submitted to ERMA New Zealand for approval) will provide a means of compliance with the labelling provisions of the group standard (see earlier submission and response).</p> <p>This statement is required for all 6.1D and 6.1E substances (clause 5.1.2.2(2)(a)) when the substance is available to members of the public. This is consistent with the regulations. However, the requirement of the HSNO identification regulations has been softened by not requiring such a warning statement in places of work where the substance will not be available to members of the public.</p>	No
<b>Compliance and other matters</b>			
10	<p>Are exposure limits really necessary for low risk products?</p> <p>Why should a 50+ kg pack require a safety data sheet and a 25 kg pack doesn't. They may well be labelled the same.</p>	<p>Exposure limits are one of the essential tools to ensure the manufacture and use of a substance is appropriately managed to protect human health and the environment.</p> <p>Group standards contain provisions for the adoption of exposure limits for toxic and ecotoxic substances. This approach is consistent with the</p>	No

Submitter	Submission comment	Agency response and recommendation	Group standards amended
		<p>requirements of the HSNO regulations. The 2005 amendment to the HSNO Act included a provision that will allow ERMA New Zealand to develop exposure limits separate from substance approvals. Exposure limits are more likely to be set for the more high risk substances (such as anthropogenic chemicals that are components of parasiticide products), rather than naturally occurring minerals.</p> <p>When quantity or volume thresholds are set (as with safety data sheets) this is always the potential anomaly that the same product in two pack sizes will be treated differently. Generally, a hazardous substance in a larger quantity poses a greater magnitude of risk than when present in comparatively smaller quantities. The 50 kg threshold proposed in the group standards has been taken directly from the Emergency Management regulations. With all group standards we have tried to align trigger quantities with those set out in the regulations.</p>	
12	<p>Blanket notification provision for new chemicals – will it be the case that if a new animal nutritional product similar in nature meets the specifications in one of these Group Standards no new approval is required?</p>	<p>Yes, provided that the new product does not contain any component that is a new chemical. By new chemical we mean a chemical that was not previously present in New Zealand. ERMA New Zealand is developing an inventory of chemicals to assist industry identify whether a chemical is an existing chemical or new to New Zealand. This inventory will be available from the ERMA New Zealand web site.</p> <p>If a company develops a new product (or reformulates an existing product) based on existing chemicals, and that new product meets the scope of the group standard, then</p> <ol style="list-style-type: none"> <li>1. no new approval from ERMA New Zealand is required, and</li> <li>2. there is no need to advise ERMA New Zealand that a new product has been deemed approved under a group standard.</li> </ol>	No
14	<p>These products are marketed by a wide range of companies and it is important for ERMA to invest in educational activities to facilitate compliance.</p> <p>We would like clarification of the time frames for compliance.</p> <p>It would be helpful to provide some written notes explaining these Group Standards in plain terms; for example that all products will have to be placed into a group Standard or deemed non hazardous, that legally they must comply with the conditions on their</p>	<p>ERMA New Zealand will be disseminating information on the establishment and compliance requirements of group standards. Work in this area has already commenced, and will continue after 1 July 2006 when group standards come into force. Information will also be provided to help companies with self-classification.</p> <p>As well as the provision of information and guidance material, we would welcome suggestions on other awareness raising initiatives, and your participation in such initiatives.</p> <p>The details of staged implementation are set out in Annex 1 of this document.</p>	No

Submitter	Submission comment	Agency response and recommendation	Group standards amended
	products, that there is an opportunity for reallocation of their products and that it is the responsibility of the proprietor to know the risk profiles and controls on their substances.		
15	<p>We don't believe it makes sense to have differing compliance timelines depending on whether a substance is imported or made in NZ as it puts NZ manufacturers at a disadvantage.</p> <p>Those industries with substances transferred individually are at a disadvantage compared with Group Standards and will incur higher compliance fees.</p>	<p>Many submitters on other group standards have also expressed concern on the potential for inequity between imported and locally manufactured products. We will look to align the compliance timelines so that domestic manufacturers are not disadvantaged. Further consultation on this issue will be undertaken.</p>	<p>Yes – depending on the outcome of additional consultation</p>

### Code to Submitters

No.	Submitter
1	Coast Biologicals Ltd
2	Interchem Agencies Ltd
3	NZ Veterinary Association Ltd
4	AGCARM
5	Vitec Nutrition Ltd
6	Federated Farmers of NZ Ltd
7	Ausrichter (NZ) Ltd
8	Vitec Nutrition Ltd
9	ACCORD Australasia
10	Vitec Nutrition Ltd
11	Cundy Technical Services Ltd
12	Ministry of Health
13	BOMAC Laboratories Ltd
14	Animal Remedy and Plant Protectant Association
15	Ancare
16	Nufarm NZ

## Annex 1: Staged Implementation for NOTS

All group standards will contain provisions for staged implementation. These provisions will apply to notified toxic substances (NOTS) that are transferred from the transitional provisions to the main framework of the HSNO Act. The purpose of staged implementation is to allow importers, manufacturers and users of animal nutritional products a period of time to become familiar with the new group standard conditions, and to progressively implement these conditions.

The key dates for staged implementation are set out in the table below.<sup>7</sup>

<b>1 July 2006</b>	NOTS transferred to HSNO. Six month period commences before any group standard conditions apply. Persons continue to comply with current regulatory requirements
<b>1 January 2007</b>	Approved handler test certificates required (either deemed <sup>1</sup> or full five year certificate) <sup>2</sup> Compliance required with all group standard conditions, with the exception of conditions for: <ul style="list-style-type: none"> <li>➤ Test certificates for hazardous substance locations<sup>2</sup></li> <li>➤ Stationary bulk container systems</li> <li>➤ Emergency management<sup>2</sup></li> <li>➤ Signage<sup>2</sup></li> <li>➤ Labelling, safety data sheets and packaging</li> </ul>
<b>1 July 2007</b>	Compliance required with emergency management conditions <sup>2</sup> (fire extinguishers, response plans and secondary containment)
<b>1 January 2008</b>	Test certificates required for hazardous substance location <sup>2</sup>
<b>1 July 2008</b>	Report required from test certifier for existing stationary bulk container systems Compliance required with conditions for: <ul style="list-style-type: none"> <li>➤ Labelling<sup>3,4</sup></li> <li>➤ Safety data sheets</li> <li>➤ Signage<sup>2</sup></li> <li>➤ Packaging</li> </ul>
<b>1 January 2009</b>	Full 5 year approved handler test certificate required
<b>1 July 2009</b>	Test certificate required for existing stationary bulk container systems
<b>31 December 2010</b>	Product labels are compliant to this date if they comply with the labelling requirements of Europe, Australia, USA or Canada <sup>4</sup>

1. A person with two years experience in handling hazardous substances can deem themselves as an approved handler to 31 December 2008.
2. Staged implementation provisions may not apply for approved handler test certificates, location test certificates, emergency management and signage if compliance is already required for a similar class of hazardous substance (see section 'If existing HSNO Provisions Apply').
3. Other than for substances that comply with the labelling requirements of Europe, Australia, USA or Canada.
4. A group standard condition proposes that a 4 year period be allowed for compliance with labelling, provided that the product labels comply with the regulatory requirements for labelling that apply in these countries. This provision will apply to new products as well as NOTS.

<sup>7</sup> These are the generic provisions applying to all NOTS covered by group standards. Some provisions (e.g. test certificate for approved handler) will not be relevant for animal nutritional products.

### **If Existing HSNO Provisions Apply**

Where existing HSNO provisions apply for approved substances (e.g. dangerous goods transferred on 1 April 2004), then there will be no staged implementation for an approved handler test certificate, location test certificate, emergency management or signage if persons are already required to hold test certificates or have emergency management provisions and signage in place for the same class of substance. In this situation, compliance should have already been achieved. Therefore, full compliance for the NOTS is required by 1 January 2007. All other provisions for staged implementation (e.g. labelling, packaging etc) will apply as set out above. Full staged implementation (including for test certificates, emergency management and signage) will apply if **new classes** of substances are transferred as NOTS.

For example, a person who imports or manufacturers a class 3.1 flammable NOTS will not receive staged implementation for test certificates, emergency management or signage if they also store class 3.1 flammables that are already HSNO approved substances and for which they require test certificates, emergency management and signage. If, however, they are manufacturing or storing NOTS that are of a different class (e.g. class 5 oxidising substances), then staged implementation will apply as set out above, but only for that new class.

### **Further Information**

Further details on staged implementation and general compliance requirements will be provided to notifiers in the lead-up to transfer. For other compliance information, you can contact the ERMA New Zealand Hazardous Substance Compliance Line, by:

Phone: 0800 376 234, or

Email: [dginfo@ermanz.govt.nz](mailto:dginfo@ermanz.govt.nz).