



**Transfer of
Substances**

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



Summary of Submissions: Group Standards for Dental Products

April 2006

Prepared: 7 April 2006

File reference: TRFR-01-02-01-28-06 dental products summary of submissions

Contents

1. INTRODUCTION	1
1.1 Background to the Consultation	1
1.2 Moving NOTS	2
1.3 Combining Group Standards	2
1.4 Approval of Group Standards	3
1.5 Further Consultation Required	3
1.6 Gazetting of Group Standards and Staged Implementation	3
2. SUBMITTER'S COMMENTS AND AGENCY RESPONSE AND RECOMMENDATIONS	4
ANNEX 1: STAGED IMPLEMENTATION FOR NOTS	7

1. Introduction

1.1 Background to the Consultation

This document reports on the submissions that were received on proposals to establish group standards for dental 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 eight group standards for dental products on 3 February 2006. Consultation closed on 21 March 2006. 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,¹ or a letter advising of the availability of these documents, were provided to approximately 50 parties who were considered likely to have an interest in this consultation. This included companies who notified dental 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.²

Two submissions were received, with one of the submitters requesting a hearing. ERMA New Zealand had further discussions with this submitter on the matters they raised in their submission, and as a consequence of these discussions, they withdrew their request for 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.

This summary of submissions has been provided to all parties who made a submission on the dental products group standards, major notifiers of dental products³ and to the Hearings Committee of the Authority.⁴ It is also available from the ERMA New Zealand web site: <http://www.ermanz.govt.nz/hs/groupstandards/standards/dental.html>. A copy will be provided to any other interested party on request. Contact:

Haromi Roberts
ERMA New Zealand
PO Box 131
Wellington, New Zealand

Phone +64 4 918 4871

Email NOTS@ermanz.govt.nz and enter "Dental Products Summary of Submissions" in the subject line.

¹ Provided electronically on CD. No paper copies were distributed unless specifically requested.

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

³ Notifiers with only a few NOTS have been advised by letter of the availability of this summary of submissions.

⁴ 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.

1.2 Moving NOTS

When group standards were released for consultation, notifiers were given a list of their products notified under the Toxic Substances Act 1979 (NOTS) associated with each standard. If a NOTS had been incorrectly assigned by ERMA New Zealand to a specific group standard, the notifier is able to reassign it to the appropriate group standard. If a notifier moves a NOTS from one group standard to another (or removes the NOTS from a group standard because they determine it to be non-hazardous) we asked in the consultation document for the notifier to advise us.

To assist notifiers reassign their NOTS, ERMA New Zealand has developed an excel template that can be accessed by emailing us at: NOTS@erманz.govt.nz.⁵ 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.

1.3 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.

For dental industry products, the Class 3.1B and 3.1C flammable group standards have been combined.

From the consultation on other sets of group standards, several submissions were received requesting that group standards be combined to reduce the number of standards 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 any more or less 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, particularly where group standards have been rolled-up across hazard (such as 3.1B and 3.1C), for some conditions, various options are presented, and the relevant option has to be chosen depending on the hazard of the substance concerned.

Parties who read the original group standard proposals will 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.

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

1.4 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.⁶

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 group standards for dental products on the 12 April 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).

1.5 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 (Class 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 early April 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.

1.6 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.

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

2. Submitter's Comments and Agency Response and Recommendations

Submitter	Submission comment	Agency response and recommendation	Group standards amended
3M	General support for applying group standards to deal with product types of similar hazard to simplify ERMA's management of hazardous substances and reduce compliance costs for industry.	Support noted	No amendment required
	The contact information (i.e. name, full address, phone No) and 24 hour emergency phone number requirements for labelling in the group standards are excessive. These requirements are not in line with GHS intentions, nor are they required by the regulations.	This proposed 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 exactly with the current regulatory requirements. Note the need for a 24 hr emergency phone number is a requirement of the Emergency Management Regulations for certain hazard classifications.	Yes – amend to align with HSNO regulations
	Agree with alternative compliance for labelling of substances, i.e. aligned with overseas trading partners adopting GHS.	Support noted	No amendment required
	Disagree with SDS requirements to provide full contact details and emergency contact. (subsection 5.1.3 (5,a,iii)) as this contradicts the current ID regulations..	The Safety Data Sheet requirements to provide contact details and an emergency contact are consistent with the requirements of regulations 39(3) and 39(4)(b) of the Hazardous Substances (Identification) Regulations, the NZCIC Code of Practice and the GHS provisions for safety data sheets.	No
	Where do products that have been matched via the SOS process fall under and how will this information be conveyed?	Substances that have been matched to NOTS via the Status of Substance (SOS) process have been recorded in our database. Companies who made these SOS applications will be advised (post 1 July 2006) of the GS under which their product is deemed approved.	No amendment required
	Dental products are oral products and it is hard to understand why they would contain chemicals of concern. Companies manufacturing dental products within the OECD are very well aware of the need to ensure that if an ingredient is likely to be harmful, its use is discontinued.	The proposed condition for Chemicals of Concern is being removed from the group standards framework. Further information is given in the consultation document to be released in early April (see section 1.5)	Yes – condition on Chemicals of Concern removed
	Require clarification when a new substance requires a Rapid Assessment. Understand that a raw material that did not alter the hazard of a substance would be defined as 'the same as'. Seek clarification where product modification reduces risk, i.e. moves from 3.1B to 3.1C.	If a 'new' substance (such as an existing substance that was reformulated) has the same hazard classification as the original product, then it is covered by the same group standard approval (presuming it is of the same application type and nothing else has been changed that would take it out side the scope of the group	No amendment required

Submitter	Submission comment	Agency response and recommendation	Group standards amended
		<p>standard). Similarly, a product that is reformatted and the hazard profile is changed will also be covered by a group standard if such a group standard exists.</p> <p>In situations where no group standard exists, a reformulated product may require a rapid assessment. The Act allows for the rapid assessment of a substance that has been formulated such that one or more of its hazardous properties has a lesser degree of hazard than any substance that has been approved under the Act.</p>	
	<p>During informal consultation the draft GS for dental products specifically excluded cosmetics in its definition of a dental product. This exclusion was removed in the documents issued for formal consultation. Query the removal of the cosmetic exclusion and believe that cosmetics such as toothpaste be included in a separate GS.</p>	<p>The definition of dental products has been updated to exclude cosmetics. Cosmetic dental products, such as toothpastes, are covered under the Cosmetic Products Group Standard.</p>	<p>Yes – definition will exclude cosmetic products</p>
	<p>Dental GS should only apply to substances used by trained dental professionals.</p>	<p>The exclusion of cosmetic products from the Dental Products Group Standards effectively achieves this outcome for the majority of products (e.g. toothpastes, teeth whiteners, mouthwashes etc.). However there are a few products that need to fit under these Group Standards (e.g. denture sterilisers) that more appropriately fit under the scope of the Dental Products Group Standards</p>	<p>No amendment required</p>
	<p>Dental products are generally small pack sizes and will not trigger the controls for Approved Handlers, Location Test Certificates, Hazardous Atmosphere Zones, Response Plans, Secondary Containment, or Signage.</p>	<p>Generally we agree. There should be little, if any, obligations on a dental practice for approved handlers (from a physical hazard), location test certificate, hazardous atmosphere zones, response plans, secondary containment or signage. However, these provisions need to be allowed for in the group standards to cover bulk storage.</p> <p>In the case of an acute toxicity hazard (6.1B/C), an approved handler requirement is triggered at any quantity. However, this should also have negligible impact on a dental practice, because where a group standard triggers an approved handler requirement for acute toxicity, that standard contains a provision deeming an oral health practitioner as an approved handler provided they hold a current annual practising certificate issued by the Dental Council of New Zealand.</p>	<p>No amendment required</p>

Submitter	Submission comment	Agency response and recommendation	Group standards amended
Dental Council of New Zealand	Length and complex subject matter of consultation document made it difficult to read and understand. It would have been helpful if the consultation document had been written in a more 'user friendly' form.	Comment acknowledged. The document needed to convey a large amount of complex information. We trust that this was not to the detriment of your submission.	No amendment required
	Consider that eight GS adequately cover full range of dental products	Noted	No amendment required
	Definition of dentistry does not cover full range of dentistry. Suggest replacement of "teeth and gums" with "orofacial complex and associated structures".	Definition updated to reflect submission made.	Yes
	Oral health professions should also include clinical dental technicians	The definition of oral health practitioners has been updated to reflect submission made.	Yes
	Notification requirement for new chemicals to NZ places considerable responsibility on, and requires significant knowledge on importers and suppliers to identify that new chemicals have been used in a product. It is not clear how the information required under this condition will be known to the importer. Will there be any guidelines for importers to ensure that they are aware of the notification condition and fully understand when and how they are expected to comply with it? The Dental Council would support a process aimed at ensuring that the [dental] industry is comprehensively informed of this notification obligation and provided with clear advice as to how and when it should be exercised.	<p>ERMA New Zealand is aware of the need to provide the necessary information and tools to support the classification of substances by industry, including compliance with the notification requirement for new chemicals. 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> <p>The provision of information and supporting tools will be a priority once group standards come into force and during the implementation period. This will include the inventory of chemicals known to be present in New Zealand, which will be available via the ERMA New Zealand web site.</p> <p>For companies who are uncertain of their obligations under a group standard, ERMA New Zealand will be offering a product classification (advice) service, which will identify substances that contain new chemicals. This service will be similar to the Status of Substance (SOS) service currently provided by ERMA New Zealand.</p>	No amendment required

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 dental 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.

1 July 2006	NOTS transferred to HSNO. Six month period commences before any group standard conditions apply. Persons continue to comply with current regulatory requirements
1 January 2007	Approved handler test certificates required (either deemed ¹ or full five year certificate) ² Compliance required with all group standard conditions, with the exception of conditions for: <ul style="list-style-type: none"> ➤ Test certificates for hazardous substance locations² ➤ Stationary bulk container systems ➤ Emergency management² ➤ Signage² ➤ Labelling, safety data sheets and packaging
1 July 2007	Compliance required with emergency management conditions ² (fire extinguishers, response plans and secondary containment)
1 January 2008	Test certificates required for hazardous substance location ²
1 July 2008	Report required from test certifier for existing stationary bulk container systems Compliance required with conditions for: <ul style="list-style-type: none"> ➤ Labelling^{3,4} ➤ Safety data sheets ➤ Signage² ➤ Packaging
1 January 2009	Full 5 year approved handler test certificate required
1 July 2009	Test certificate required for existing stationary bulk container systems
31 December 2010	Product labels are compliant to this date if they comply with the labelling requirements of Europe, Australia, USA or Canada ⁴

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.

If Existing HSNO Provisions Apply

Where existing HSNO provisions apply, 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 with these requirements 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 the person is dealing with **new classes** of substances.

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 they are already required to have the necessary test certificates, and emergency management and signage provisions in place for those approvals. If, however, they are manufacturing or storing a different class of substance for the first time (class 5 oxidising substances, for example), 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.