



**Transfer of
Substances**

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO



Summary of Submissions: Group Standards for Fragrance Materials

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 fragrance materials. 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 seven group standards for fragrance materials on 23 November 2005. Consultation closed on 31 January 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 80 parties who were considered likely to have an interest in this consultation. This included companies who notified fragrance materials 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.²

Four 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.

Half of the submissions related to certain notified products (NOTS) which had been placed in the wrong group standard and it was requested that they be moved to the correct group standard (see Section 1.2)

This summary of submissions has been provided to all parties who made a submission on the fragrance materials group standard proposals, all notifiers of fragrance materials (whether or not they made a submission) and to the Hearings Committee of the Authority.³ It is also available from the ERMA New Zealand web site: <http://www.ermanz.govt.nz/consultations/gs/fragrances.asp>. A copy will be provided to any other interested party on request. Contact:

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Email NOTS@ermanz.govt.nz and enter “Fragrance Materials 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/fragrances.asp>.

³ 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

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.⁴ 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 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 fragrance materials these have been combined with food additives and renamed as *Food Additives and Fragrance Materials Group Standards*. Similarly, the Class 3.1B and 3.1C flammable group standards have been combined.

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 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, 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 selected 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.

⁴ 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.⁵

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 Food Additives and Fragrance Materials on the 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).

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 (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.

1.6 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.

⁵ Group standards that were consulted on will be amended as indicated in Section 2.

2. Submitter's Comments and Agency Response and Recommendation

Submitter	Submission comment	Agency response and recommendation	Group standards amended
Ministry of Health	<p>Generally support the conditions specified on the HSNO draft Gazette Notices and agree they are more user-friendly.</p> <p>Support the use of prescriptive statements on labels, e.g. 'Keep Out of Reach of Children', and supportive of the address of the manufacturer/importer being on a label, especially from an enforcement point of view.</p> <p>Will the additional prescriptive labelling apply to substances other than in transfer?</p> <p>Are there perfumes which meet any of the HSNO thresholds? If there are, how would they be labelled advertised etc?</p>	<p>Support noted.</p> <p>Support noted.</p> <p>For any substance that is deemed approved under a group standard, whether it is an existing substance in transfer or a new substance that fits the scope of the group standard, the additional prescriptive labelling will apply.</p> <p>For substances that already have HSNO approvals by means other than group standards (e.g. a Part V approval) the existing controls given to that substance at the time of their approval will continue to apply. However, companies can use these prescriptive statements as a means of compliance with the controls.</p> <p>Yes. To be controlled by the HSNO Act they must meet at least one of the HSNO thresholds. The requirements, as set out in the draft group standard conditions, will apply to them. In some cases, particularly when the material is present in small quantities (e.g. retail pack sizes) some of the more rigorous requirements (such as approved handler for highly flammable materials) will not apply. Perfumes will also be covered by the cosmetics group standard that is shortly to be released for consultation.</p>	<p>No amendment required</p> <p>No amendment required</p> <p>No amendment required</p> <p>No amendment required</p>

Submitter	Submission comment	Agency response and recommendation	Group standards amended
<p>Employers and Manufacturers' Association (N) Inc</p>	<p><i>Overseas legislative interface</i></p> <p>Support the provision recognising the labelling and packaging of our major trading partners. However, believe the 2010 sunset clause should be reviewed for possible extension upon expiry to ensure implementation of GHS in overseas jurisdictions matches New Zealand. Want clearer statement within GS to this effect.</p> <p>Concern expressed that local manufacturers must comply with labelling regardless of 2010 clause.</p> <p>New Zealand specific information is specific to New Zealand only labelling. Not in line with GHS intentions.</p> <p>24 hour emergency phone is equally met by national poisons centre in case of toxic substance.</p> <p><i>MSDS requirements</i></p> <p>EMA wants simplification of SDS to remove requirement for HSNO approval numbers.</p> <p>The disposal and handling regulations are not GS compliant. For higher risk substances there needs to be a fall back to the regulatory requirements.</p>	<p>Support noted. The 2010 date has been set based on current expectations of when the GHS will be adopted internationally. A review based on any delay in implementation of GHS globally would only be contemplated in response to that circumstance occurring. The inclusion of a statement to this effect in the group standard is unnecessary.</p> <p>The dates will be aligned so that all products (locally manufactured and imported) will receive the 2010 provision provided that they comply with the labelling requirements in Europe, Australia, USA or Canada. Further consultation on this issue will be undertaken.</p> <p>New Zealand specific labelling is appropriate for products sold in New Zealand and available to the New Zealand public. To allow for progressive implementation and minimise compliance costs, a 4 year period is given to overseas products. As noted above, we are looking to extend this 4 year provision to locally manufactured products.</p> <p>The need for a 24 hr emergency phone number is a requirement of the Emergency Management Regulations. The wording of this condition is to be amended so that the requirement applies only to specified hazards. Providing the call-free poisons centre number on a product label is one means of compliance with the group standard condition.</p> <p>The inclusion of local regulatory information on a safety data sheet is consistent with international best practice, the NZCIC Code of Practice for SDS, and the GHS. Providing information to show that a substance is HSNO approved will assist compliance and enforcement initiatives. As a result of other submissions, the wording of the particular condition will be amended to allow for <i>either</i> the HSNO approval number or the name of the group standard to be provided on the SDS.</p> <p>The disposal and handling conditions of the group standard are based on the HSNO regulations, which are designed to manage all levels of risk of a hazardous substance. These</p>	<p>No</p> <p>Yes, our current intention. Note that further consultation will be undertaken</p> <p>No</p> <p>Yes – wording amended to align with HSNO regulations.</p> <p>Yes – wording amended, but requirement for indication of HSNO approval remains.</p> <p>No</p>

Submitter	Submission comment	Agency response and recommendation	Group standards amended
	<p><i>Advertising</i> Advertising section perceived as unworkable for business as it imposes unnecessary regulatory burden for no appreciable gain in risk prevention. Questions asked as to who will enforce this requirement. Suggest this requirement should be removed from group standards</p> <p><i>Approved handler requirements</i> The approved handler requirement where this is specified has no threshold and we believe a trigger threshold should apply to avoid unnecessary compliance costs.</p> <p><i>Packaging</i> There is little or no justification for Child Resistant packaging due to the nature of the products and the small volumes of diluted products that are ultimately retailed to consumers.</p>	<p>conditions are non prescriptive and therefore allow for a variety of means of compliance. The NZCIC are developing a code of practice to assist compliance with the HSNO disposal requirements.</p> <p>The requirement for identification of acutely toxic materials in advertisements is based on requirements that previously applied to similar substances under the Toxic Substances Regulations 1983, and which is currently reflected in the HSNO Identification regulations. It is not appropriate to take this off substances that previously had such controls. The condition only applies when advertising is to members of the public, and it is reasonable that the public is informed when a product is acutely toxic and/or corrosive. Enforcement will rest with existing enforcement agencies.</p> <p>The approved handler requirements are retained (other than for an ecotoxicity hazard), but users need to consider whether the quantities held are sufficient to trigger this condition. For flammability, thresholds are set in the group standard, and these are adopted unchanged from the HSNO (Classes 1 to 5 Controls) Regulations. For acute toxicity and corrosivity, no threshold is set, again consistent with the HSNO regulations. It is appropriate that this control, which is applied only to the most severe hazards, is aligned with the regulations. For ecotoxicity, no approved handler requirement has been applied and this is valid given the non-dispersive use of these substances.</p> <p>The requirement for child resistant packaging for acutely toxic and corrosive substances is appropriate, and will be retained. We agree that the CRP requirement for irritancy is more questionable, and we will be reviewing this control, including undertaking a further round of consultation (see Section 1.6). Note that the group standard will contain staged implementation provisions for packaging (see Annex 1).</p>	<p>No</p> <p>No</p> <p>Dependant on outcome of additional consultation</p>

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 fragrance materials 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.