

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

23 April 2007

Purpose of the Application	To amend the <i>Denatured Ethanol Group Standard 2006</i> to give effect to the decision of the Authority on the Reassessment of methylated spirits (HRC000002)
Applicant	ERMA New Zealand
Date Application Notified	22 February 2007
Consideration Date	20 April 2007
Considered by	A Committee of the Authority

1 Summary of decision

- 1.1 The amendment to the *Denatured Ethanol Group Standard 2006* to effect the outcome of the methylated spirits reassessment and remove the provision allowing for denatured ethanol formulations containing methanol to be sold to the general public is **approved** in accordance with the relevant provisions of the Act, the HSNO Regulations and the HSNO (Methodology) Order 1998 (the Methodology).
- 1.2 Clause 4(5) of the *Denatured Ethanol Group Standard 2006* is omitted and substituted with the following clause:
- (5) Notwithstanding subclause (4), a substance that is available for sale to the general public—
- (i) must only be denatured with the specific formulations described in subclauses 4(e) and (g); and
- (ii) should, where practicable, also contain at least 1.56 ppm methyl violet provided that a substance that is available for sale to the general public may be denatured with the specific formulation designated in subclause (4)(f) up until the close of 21 June 2007.

2 Legislative criteria for the application

- 2.1 The need for this amendment to the *Denatured Ethanol Group Standard 2006* was identified by the Agency following the reassessment of methylated spirits (HRC000002), whereby the Authority decided that formulations of denatured ethanol sold to the general public should not be permitted to contain methanol from 21 June 2007.
- 2.2 This decision to amend the *Denatured Ethanol Group Standard 2006* was determined in accordance with section 96C, taking into account matters relevant to the purpose of the Act specified under Part II of the Act. Unless otherwise stated, references to

section numbers in this decision refer to sections of the Act. To the extent necessary, consideration of the amendment to the *Denatured Ethanol Group Standard 2006* followed the relevant provisions of the Methodology. Unless otherwise stated, references to clauses in this decision refer to clauses of the Methodology.

3 Application process

- 3.1 In accordance with section 96C(1)(h), public notification was made on 22 February 2007.
- 3.2 Submissions closed on 5 April 2007.
- 3.3 Various government departments (including the Ministry for the Environment, Ministry of Health, the Department of Labour, the New Zealand Food Safety Authority and the New Zealand Customs Service), Crown entities and interested parties, which in the opinion of the Agency would be likely to have an interest in the application, were notified of the receipt of the application (sections 53(4) and 58(1)(c), and clauses 2(2)(e) and 5) and provided with an opportunity to comment or make a public submission on the application.
- 3.4 No comments were received. However, it is noted that the Ministry of Health responded to the methylated spirits reassessment as follows:
- “The Ministry agrees with ERMA NZ’s recommendation for total exclusion of methanol from retail methylated spirits given the effects of abuse of this product and that the sale or supply of methylated spirits be restricted to industrial or commercial situations. The proposal is consistent with the Ministry of Health’s intention of minimising methylated spirits related poisoning.”*
- 3.5 One submission was received in opposition to the proposal.
- 3.6 A public hearing was not required to be held.
- 3.7 The following members of the Authority considered the application (section 19(2)(b)): George Clark; (Chair) Kieran Elborough; Deborah Read.
- 3.8 The Agency prepared a consideration paper to aid the Committee in its decision making process. The consideration paper addressed the matters referred to in sections 96B and 96C and the sole submission received during the consultation period.
- 3.9 The information available to the Committee comprised:
- the consideration paper;
 - the *Denatured Ethanol Group Standard 2006* showing the proposed changes;
 - the one submission received;
 - the decision on the methylated spirits reassessment.

4 Consideration

Purpose of the application

- 4.1 The purpose of the amendment to the *Denatured Ethanol Group Standard 2006* is to give effect to the Authority’s decision on the methylated spirits reassessment,

namely that formulations of denatured ethanol sold to the general public should not be permitted to contain methanol from 21 June 2007.

Sequence of the consideration

- 4.2 In accordance with clause 24, the approach adopted by the Committee was to:
- identify the amendments to the *Denatured Ethanol Group Standard 2006* to be considered by the Authority;
 - consider the matters that the Authority needs to be satisfied with under Part 6A of the Act to amend this group standard;
 - confirm that the Agency's internal quality assurance process has been undertaken; and
 - reach a decision on the proposed amendment to the *Denatured Ethanol Group Standard 2006*.

Proposed amendments

- 4.3 The proposed amendment to the *Denatured Ethanol Group Standard 2006* is to omit the existing clause 4(5) of the group standard, and substitute the following new clause:

- (5) *Notwithstanding subclause (4), a substance that is available for sale to the general public—*
- (a) *must only be denatured with the specific formulations described in subclauses 4(e) and (g); and*
 - (b) *should, where practicable, also contain at least 1.56 ppm methyl violet*
- provided that a substance that is available for sale to the general public may be denatured with the specific formulation designated in subclause (4)(f) up until the close of 21 June 2007.*

Requirements of Part 6A of the Act

Public notification

- 4.4 Before amending a group standard, section 96C(1)(h) requires the Authority to publicly notify—
- (i) the proposal to amend the group standard; and
 - (ii) its assessment of the matters required under subsections (1)(a), (b), (c), (d) and (e) in relation to the group standard as proposed to be amended¹
- 4.5 A public notice was placed in the main metropolitan newspapers (New Zealand Herald, Dominion Post, Christchurch Press and the Otago Daily Times) indicating the release for consultation of an amendment to the *Denatured Ethanol Group Standard 2006*.
- 4.6 Release of this proposal was also notified on the ERMA New Zealand website on 22 February 2007. The consultation document was available from the consultation page of the website from that date.

¹ These are the matters that relate to efficiency and effectiveness, nature, type or circumstance of use, international practices and standards, and controls under sections 77, 77A and 77B.

- 4.7 As required under the Act, thirty working days were allowed from the release of the proposed amendment to the *Denatured Ethanol Group Standard 2006* on the website for the receipt of submissions. The submission period ran from 22 February 2007 to 5 April 2007.
- 4.8 The consultation document included a submission form and explained the process for making a submission. One submission was received.

More efficient and effective

- 4.9 Before amending a group standard, sections 96C(1)(a), (b) and (c) require the Authority to be satisfied that amending the group standard is a more efficient and effective way of managing the risks of all the hazardous substances in the identified group.
- 4.10 The proposed amendment to the group standard (removing the use of methanol as a denaturant in formulations sold to the general public) is considered to be a more effective way of managing the risks associated with denatured ethanol. Methanol acts as a denaturant by virtue of being a poison. However, many chronic alcohol abusers are drinking methylated spirits regardless of the addition of methanol and are consequently suffering the adverse effects. Chemical Injury Surveillance Reports prepared by ESR for the Ministry of Health attributed the deaths of three people in 2002-03 to drinking methylated spirits, while a total of 24 poisonings involving methylated spirits were recorded in Auckland City, Hutt, Wellington, Kenepuru, Masterton, Grey and Invercargill Hospitals during 2005. Consequently, in its decision on the reassessment of methylated spirits (HRC0000002) the Authority decided that the risks of methylated spirits could be better managed by making it unavailable to the general public, given that there are safer alternative denaturants available. These alternative denaturants act as denaturants not by virtue of their poisonous nature, but rather by virtue of their emetic and bitter properties.
- 4.11 The proposed amendment to the group standard (removing the use of methanol as a denaturant in formulations sold to the general public) is also considered to be a more efficient way of managing the risks associated with denatured ethanol. The Authority notes that one supplier indicated that the formulation of ethanol denatured with 15.6 ppm denatonium benzoate would cost an additional one cent per litre to produce compared with the formulation containing methanol and denatonium benzoate. However, notwithstanding this small potential increase in production costs, the Authority believes that when all the benefits of the amendment are considered, they outweigh the costs (both tangible and intangible) on people and communities.

One set of conditions for similar nature, type, or circumstance of use

- 4.12 Before amending a group standard, section 96C(1)(e) requires that the Authority be satisfied that if the group standard applies to more than 1 hazardous substance or product, all the hazardous substances or products have a similar nature, or are of a similar type, or have similar circumstances of use, such that the risks of the group of hazardous substances or products can be effectively managed by 1 set of conditions.
- 4.13 All of the existing forms of denatured ethanol have been grouped on the basis of their similar nature in accordance with the requirements of Part 6A of the Act for

establishing a group standard. The hazardous substances covered in this group standard are all solutions of more than 90% ethanol that have been denatured with defined denaturants so as to be unfit for human consumption. Consequently, all of these substances have similar chemical and physical properties. A key property which they all share, and in which they differ from other forms of ethanol, is that they have been denatured so as to be unfit for human consumption.

- 4.14 The proposed amendment will further restrict this narrow scope, such that denatured ethanol formulations will no longer be permitted to be denatured with the following denaturants in combination when sold to the general public:
- 10 ppm denatonium benzoate together with the addition of at least 1.5% and not more than 2% by volume methanol.

International practices and standards

- 4.15 Before issuing or amending a group standard, section 96C(1)(f) requires that the Authority consider the best international practices and standards for the safe management of hazardous substances and products.
- 4.16 In this regard, the Agency notes that denatured ethanol formulations containing methanol are not available to the general public in Australia.

Controls under sections 77, 77A and 77B

- 4.17 Before issuing or amending a group standard, section 96C(1)(g) requires that the Authority consider the types of controls appropriate for the group in accordance with sections 77, 77A and 77B.
- 4.18 The Agency does not consider it is necessary to consider the variation of controls under sections 77, 77A and 77B as the conditions within this group standard will remain unchanged from those previously decided upon.

Quality Assurance Process

- 4.19 As required by the Internal Quality Assurance System for the amending of deemed regulations, approved by the Authority in August 2006, this amendment was formally 'certified' by Manager, Legal & Risk stating compliance with the following matters:
- 4.19.1 The amendment (and the deemed regulation) is within the empowering provisions of the Act (namely, section 96B).
- 4.19.2 The amendment has no effect on the principles of the Treaty of Waitangi.
- 4.19.3 The amendment has no effect on the rights and freedoms guaranteed by the New Zealand Bill of Rights Act 1990 and Human Rights Act 1993.
- 4.19.4 The amendment complies with the privacy principles in the Privacy Act 1993.
- 4.19.5 The amendment has no effect on New Zealand's international obligations.
- 4.19.6 The amendment will only come into force 28 days after being published in the *Gazette*.

- 4.19.7 The wording of the amendment and the associated *Gazette* notice have been drafted by Manager, Legal & Risk and raises no issues which need to be drawn to the attention of the House by the Regulations Review Committee pursuant to Standing Order 378.

5 Decision

The Committee, having considered the application to amend the *Denatured Ethanol Group Standard 2006* made under section 96B of the Act, **approves** the proposed amendment to the *Denatured Ethanol Group Standard 2006* and to its publication in the *New Zealand Gazette*, noting that the amendment to the *Denatured Ethanol Group Standard 2006* will come into force 28 days after the date of publication in the *Gazette*.

George Clark

Date: 23 April 2007

Chair