



Environmental  
Protection Authority  
*Te Mana Rauhi Taiao*

# Proposals for Amendments to the Cosmetic Products Group Standard

November 2011



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## 1. Background

- 1.1. The original Cosmetic Products Group Standard (HSNO Approval No. HSR002552) was established on 1 July 2006. Since its establishment, the Cosmetic Products Group Standard has been amended three times; in July 2008, July 2009 and November 2010, as well as a minor amendment to a technical error in November 2011. The full text of the amended group standard is available on the EPA web site<sup>1</sup>.
- 1.2. The EPA is now releasing for consultation a suite of proposals for further amendments to the Cosmetic Products Group Standard.

## 2. Basis for the proposed amendments

- 2.1. The Cosmetic Products Group Standard is closely based on the European Union (EU) Cosmetics Directive (76/768/EEC)<sup>2</sup>, which is itself amended several times every year. The schedules to the Cosmetic Products Group Standard setting out components that are not permitted or permitted with restrictions are based primarily on corresponding Annexes from the EU Directive. Therefore, some of the proposals take account of amendments made by the EU to the Cosmetics Directive since the last substantial amendment to the Cosmetic Products Group Standard in November 2010.
- 2.2. On 30 November 2009, the new Cosmetic Products Regulation (EU Regulation 1223/2009) was adopted, replacing the Cosmetics Directive. The new Cosmetics Regulation reinforces product safety taking into consideration the latest technological developments, including the possible use of nanomaterials.
- 2.3. The Cosmetics Directive and the new Cosmetics Regulation are applicable successively, meaning that as of 11 July 2013, when the Cosmetics Regulation is applicable, the Cosmetics Directive is repealed.
- 2.4. On this basis, proposals based on actions in the EU legislation are based on both the Directive and the Regulation, and are identified as such.
- 2.5. The EPA is also proposing several amendments are made to the Cosmetic Products Group Standard in order to improve clarity of the group standard requirements.

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<sup>1</sup> <http://www.epa.govt.nz/Publications/gs-cosmetic.pdf>

<sup>2</sup> The full text of the EU Cosmetics Directive can be accessed online at:  
[http://ec.europa.eu/consumers/sectors/cosmetics/documents/directive/index\\_en.htm](http://ec.europa.eu/consumers/sectors/cosmetics/documents/directive/index_en.htm)

## 3. The Proposed Amendments

- 3.1. The proposed amendments are presented according to the order in which they appear in the group standard. A track changes version of the Cosmetic Products Group Standard is available, showing where each of the proposed changes is to be made.

### Proposal 1:

**Amend the wording of clause 4(4)(b) in the scope of the Group Standard to:**

***“This group standard excludes any cosmetic product that contains –***

***...***

***(b) a component listed in column ‘b’ of Table 1 of Schedule 5, unless the product:***

***(i) is for a purpose or use specified in column ‘c’ (if any); and***

***(ii) meets the corresponding requirements and limitations specified in columns ‘d’, ‘e’, and ‘f’.”***

- 3.2. This amendment is proposed in order to clarify of the interpretation of Schedule 5 (Components cosmetic products must not contain except subject to the restrictions and conditions laid down). The current wording is open to the interpretation that there are no restrictions on the use of components in products for purposes or uses **not** listed in column ‘c’.

### Proposal 2:

**Labelling should include all manufacturers’ original source or batch code information to ensure consumers or regulators can identify any product subject to recall.**

- 3.3. This proposal is in line with EU Cosmetics Regulation, Article 19 (Labelling) and Article 6 (Obligations of distributors).
- 3.4. Should an adverse reaction occur with any cosmetic product, having this information would allow suppliers to check with the manufacturer for any similar occurrences which might trigger both safety audits and/or a recall. If that information is not available then suppliers have no ability to track such occurrences and to assure themselves that the product in the market is safe.

### Proposal 3:

**Where nanomaterials are present, their presence must be clearly indicated on the list of ingredients and the names of such ingredients be followed by the word ‘nano’ in brackets.**

- 3.5. This proposal is in line with EU Cosmetics Regulation, Article 19 (Labelling).
- 3.6. This provides consumers with information on nano-containing products.

## Proposal 4:

**If, after placing a cosmetic product on the New Zealand market, a manufacturer or importer or distributor becomes aware that the cosmetic product presents a risk to human health, the importer or manufacturer must notify the EPA and provide details of the non-compliance and corrective measures taken.**

- 3.7. This proposal is in line with EU Cosmetics Regulation, Article 5 (Obligations of responsible persons)
- 3.8. This enables regulatory authorities to facilitate the management of non-compliant products and enables collection of vital information on compliance.

## Proposal 5:

**Amend Schedule 4 entry 46 to read “Barium salts, with the exception of barium sulphide under the conditions laid down in Schedule 5, and of barium sulfate, lakes, salts and pigments prepared from colouring agents when listed in Schedule 6”.**

- 3.9. As currently written, entry 46 prohibits the use of barium in cosmetics except as specified under entry 23 in Schedule 5. However, the use of insoluble barium lakes, salts and pigments as colouring agents is allowed for in Schedule 6.

## Proposal 6:

**Remove the ‘expiry date’ from Table 3 in Schedule 5.**

- 3.10. Table 3 in Schedule 5 lists components that are under review by the EU. By including an expiry date they may become prohibited in New Zealand before the EU reviews are completed. To keep the group standard in line with the EU, the EPA considers that the expiry date should be removed. Changes to the status of these components as a result of reviews in the EU will be reflected in future amendments to the group standard.

## Proposal 7:

**Adopt the EU definitions for ‘preservative’, ‘colorant’ and ‘UV-filter’.**

**‘preservatives’** means substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product;

**‘colorants’** means substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants;

**‘UV-filters’** means substances which are exclusively or mainly intended to protect the skin against certain UV radiation by absorbing, reflecting or scattering UV radiation.

3.11. This proposal is in line with the EU Cosmetics Regulation Article 2.

### Proposal 8:

**Delete entries 3-6, 11, 12, 16, 19-22, 25, 27, 31-33, 35-39, 44, 48, 49, 55 and 56 from Schedule 5 Table 3 and add them to Table 1 of that Schedule.**

3.12. The substances at the above entries in Schedule 5 Table 3 were temporarily allowed in cosmetics pending submission of safety data to the EU’s Scientific Committee on Consumer Products (SCCP), subsequently replaced by the SCCS (Scientific Committee on Consumer Safety). The SCCP has since finalised its assessment and determined the substances may be used as ingredients in cosmetics with the restrictions indicated in Table 1.

### Proposal 9:

**Delete entry 34 from Schedule 5 Table 3 and add it to Schedule 4 as entry 1372.**

3.13. The substance at the above entry in Schedule 5 Table 3 was temporarily allowed in cosmetics pending submission of safety data to the SCCP. The SCCP has since finalised its assessment and determined the substance cannot be considered safe when used in hair dye products, and should therefore be listed in Schedule 4.

### Proposal 10:

**Update Schedule 6 with chemical names of the colouring agents to match Annex IV of the EU’s Regulation No 1223/2009 on Cosmetic Products.**

3.14. This proposal is in line with the EU Cosmetics Regulation, Annex IV.

## 4. The EPA's assessment

- 4.1. Before amending a group standard, the EPA must:
- a. be satisfied that the Group Standard is a more efficient and effective way of managing the risks of all the substances in the group;
  - b. be satisfied that all the substances or products in the group standard have a similar nature, are of a similar type, or have a similar circumstance of use, such that the risks of the substances or products can be effectively managed by one set of conditions;
  - c. consider best international practices and standards for the safe management of hazardous substances; and
  - d. consider the types of controls appropriate for the group in accordance with sections 77, 77A and 77B of the HSNO Act.
- 4.2. The EPA's assessment of these matters follows.

### Efficiency and Effectiveness

- 4.3. The EPA consider a group standard for cosmetic products is a more efficient and effective instrument for managing the risks associated with these substances compared with issuing individual approvals for each substance under Part 5 of the HSNO Act. It allows importers and manufacturers to determine whether or not their products comply with the group standard, and what they must do to achieve compliance without the requirement of lodging applications with the EPA.
- 4.4. It is also considered that the proposed amendments will maintain the efficiency and effectiveness of the group standard by enabling products manufactured in comparable jurisdictions to continue to be marketed in New Zealand without repackaging. The EPA believes that the amendments will ensure there are no barriers to trade while at the same time safeguarding public health. Maintaining regulatory consistency may also provide market access opportunities for locally manufactured products which could be sold overseas without the need for relabeling.

### One Set of Conditions for Similar Nature, Type, or Circumstance of Use

- 4.5. The EPA considers that the proposed amendments would have no effect on the similar nature characteristic of substances that are currently covered by these group standards.
- 4.6. That the cosmetic products covered by the group standard are of a similar nature, type or use such that they were appropriate for inclusion in the Cosmetic Products Group Standard was established at the time the group standard was first issued in 2006. This proposed amendment has little effect on the scope of the substances covered by this group standard. Substances that fall within this Group Standard will continue to be of a similar nature, type and circumstance of use.

## Best International Practices and Standards

- 4.7. The EPA has considered standards established in other jurisdictions for the purposes of managing the risks associated with cosmetic products that are, or contain hazardous substances and is of the view that the proposed amendments reflect best international practice.
- 4.8. Some of the proposed amendments are prompted by changes to the EU Cosmetics Directive. These changes to the Cosmetic Products Group Standard reflect best international approaches to the management of cosmetic products.
- 4.9. With reference to **Proposal 2** it is noted that this amendment is already required for Australia (General Consumer Product Labelling), US (FDA Cosmetics and Drugs Labelling) and the EU (Cosmetic Directive Article 6 Paragraph 1.e) in terms of product labelling and therefore is consistent with best international practice. ISO 22716 for Good Manufacturing Practice establishes the need for batch identification at point of manufacture. ISO 22715:2006 sets out labelling and packaging practices internationally and states that should this be done and where required by national regulation must be done.
- 4.10. If the changes are not made, the regulation and management of cosmetic products in New Zealand will be less aligned with international practice. However, it should be noted that it is not possible to be in alignment with all jurisdictions due to a lack of consistency in overseas requirements. The EPA considers that adoption of the proposals will maximise the degree of consistency while achieving the stated aims of the Group Standard.

## Other issues

- 4.11. The Sustainability Council of New Zealand has called for a review of the definition of nanoscale.
- 4.12. The Council believes that the current definition does not cover the possible risks associated with nanomaterials, and that the economic costs of redefining 'nano' in the CPGS to properly reflect the risk are costs that manufacturers and importers should simply be required to bear as conditions of their 'licence to operate'.
- 4.13. In response to the same proposal put forward by the Council in 2010 for a risk-relevant definition to be developed, the Authority stated:

*Having a local definition may introduce significant divergence from the EU Cosmetics Directive. Given that we rely on the EU's assessment of cosmetic ingredients, any significant departure from the EU Cosmetics Directive will make it harder to adopt risk assessment applying to nanomaterials.<sup>3</sup>*

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<sup>3</sup> ERMA. 2010. ERMA200265 – Proposed amendment of the Cosmetic Products Group Standard 2006. Consideration of the Agency's proposal to amend the Cosmetic Products Group Standard 2006, p. 23.



- 4.14. This is still the view of the EPA. Because of the serious adverse effect a change of definition could have, this proposal is not supported by the EPA, and therefore has not been put forward as a proposal for consultation.
- 4.15. The EPA acknowledges the recently released recommendation from the European Commission with regards to a regulatory definition of a nanomaterial<sup>4</sup>. It is noted that this definition is based solely on the size of the constituent particles of a material, without regard to hazard or risk. It also covers natural, incidental or manufactured materials.
- 4.16. The EPA will continue to monitor the regulatory contexts in which this definition is adopted, as well as other ongoing efforts towards the development of an internationally uniform definition for nanomaterials.
- 4.17. The Sustainability Council of New Zealand also proposed that that nanoscale titanium dioxide (TiO<sub>2</sub>) and zinc oxide (ZnO) be included in mandatory labelling requirements. The EPA considers that this issue is addressed by Proposal 3:

*Where nanomaterials are present, their presence must be clearly indicated on the list of ingredients and the names of such ingredients be followed by the word 'nano' in brackets.*

## 5. The Next Steps

### Consultation

- 5.1. The EPA is notifying the proposals for public submission by way of this consultation paper.
- 5.2. Any person may make a written submission on the proposed amendments. A submission:
- shall state the reasons for making the submission;
  - may state any decision sought; and
  - shall state whether the person making the submission wishes to be heard.

### Following Consultation

- 5.3. Following consultation on the proposals to amend the group standard:
- Each written submission will be reviewed;
  - A summary of submissions will be prepared and sent to all submitters and placed on the EPA web site;
  - If required, a hearing will be held.

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<sup>4</sup> European Commission recommendation on the definition of nanomaterial can be accessed online; [http://ec.europa.eu/environment/chemicals/nanotech/pdf/commission\\_recommendation.pdf](http://ec.europa.eu/environment/chemicals/nanotech/pdf/commission_recommendation.pdf)

- 5.4. Following consideration of the submissions, any amendments to the group standard will be made by notice in the *Gazette*.
- 5.5. As soon as practicable after amending the group standard, the EPA will:
  - a. publish the group standard amendments in a publication relevant to affected persons; and
  - b. make the group standard amendments available to be inspected free of charge; and
  - c. give public notice of where the group standard amendments can be inspected.

### When the amendments to the group standard come into force

- 5.6. If approved, amendments to Group Standards normally come into force 28 days after the date on which they are notified in the New Zealand Gazette.
- 5.7. Due to the changes applying to a wide range of substances, and as some amendments are based on the EU Cosmetics Regulation which does not come into force until July 2013, a period of staged implementation is proposed.
- 5.8. The duration of the transition period will be determined by the EPA as part of the consideration of proposals to amend this group standard.
- 5.9. Comments on the appropriate implementation date of any proposal may be incorporated in a submission on that proposal.

## How to have your say

Your feedback on the proposed amendments to the group standard that are presented in this consultation document is important in ensuring that the risks involved are adequately managed under the Hazardous Substances and New Organisms (HSNO) Act 1996.

Please take this opportunity to have your say on this amendment to the Group Standard.

You can provide comment by making a submission on your own behalf or as a member of an organisation.

The submissions received will be summarised and presented to the EPA in a Summary of Submissions document, together with the proposals to amend this Group Standard. If approved by the EPA, the amendments to the Group Standard will be published in the *New Zealand Gazette*.

You can make a submission by writing your comments on the submission form entitled 'Making a Submission' on the following page of this document. Submissions can be made by mail, fax or email and should be addressed to:

Aimee Saunders  
EPA New Zealand  
PO Box 131  
Wellington  
Fax: 04 9140433  
Email: [aimee.saunders@epa.govt.nz](mailto:aimee.saunders@epa.govt.nz)

**All submissions must be received by 5 pm, Tuesday 31 January 2012.**

For any queries on this amendment to the group standards contact;

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