



**Australian Government**  
**Department of Health and Ageing**  
NICNAS

## **National Industrial Chemicals Notification and Assessment Scheme**

NICNAS proposal to adopt the revised Australian/New Zealand Sunscreen Standard (*AS/NZS 2604:2012 Sunscreen products – Evaluation and classification*) for cosmetic sunscreen products

*Summary of outcomes from consultation held  
between 4 December 2012 and 25 January 2013*

*April 2013*

## About this report

This report summarises the findings of a consultation process conducted by NICNAS on the regulatory impacts on industry, community, and government of the proposed adoption of the revised Australian and New Zealand Sunscreen Standard (AS/NZS 2604:2012 *Sunscreen products – Evaluation and classification*) in the *Cosmetics Standard 2007*. A notice on the consultation was published in the Chemical Gazette of 4 December 2012 and a reminder notice was also published in the Chemical Gazette of 2 January 2013.

The consultation process was conducted from 4 December 2012 to 25 January 2013 and was designed to seek feedback about the proposal to adopt the revised Sunscreen Standard 2012. Feedback was sought through a consultation paper seeking written responses in the form of a questionnaire sheet.

The outcomes of the consultation will inform a Government decision about the proposed adoption of the revised Sunscreen Standard 2012 for cosmetic sunscreens.

The key findings from the consultation are outlined in this report.

## Background to the consultation

In Australia, cosmetics are regulated by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the *Industrial Chemicals (Notification and Assessment) Act 1989* and the *Industrial Chemicals (Notification and Assessment) Regulations 1990*. In addition, cosmetic sunscreens (including face and nail and skin care products) must also comply with relevant aspects of the Australian/New Zealand sunscreen standard *AS/NZS 2604:1998 Sunscreen products – Evaluation and classification* (the Sunscreen Standard 1998) referenced in the *Cosmetics Standard 2007*.

Standards Australia and Standards New Zealand published a revised sunscreen standard *AS/NZS 2604:2012 Sunscreen products – Evaluation and classification* (the Sunscreen Standard 2012) on 30 May 2012, following extensive consultation with stakeholders.

The Therapeutic Goods Administration (TGA) amended the *Therapeutic Goods Regulation 1990* on 13 November 2012 to recognise the revised Sunscreen Standard (AS/NZS 2604:2012) as the legal requirement for new therapeutic sunscreens being listed on the Australian Register of Therapeutic Goods (ARTG). The TGA has also allowed the sunscreens currently listed in the ARTG, complying with the old Sunscreen Standard (AS/NZS 2604:1998), to remain listed.

NICNAS is considering whether the *Cosmetics Standard 2007* should adopt the revised Sunscreen Standard 2012.

If the revised Sunscreen Standard 2012 was also adopted by NICNAS, higher-performing broad spectrum cosmetic sunscreen products could be allowed onto the Australian market labelled as such, and there would be a consistent application of the revised Sunscreen Standard 2012 across products regulated by NICNAS and the TGA.

Therefore, the purpose of this consultation was to assess any regulatory impacts on businesses, community, and government of a proposal by NICNAS to adopt the revised Australian and New Zealand Sunscreen Standard (AS/NZS 2604:2012) in the *Cosmetics Standard 2007*. If adopted in the *Cosmetic Standard 2007*, the revised Sunscreen Standard would be applicable to all cosmetic sunscreen products regulated by NICNAS.

The consultation will allow the Government to make a decision about adoption of the revised Sunscreen Standard 2012 for cosmetic sunscreens.

## Consultation process

The consultation process was conducted through the publication of a consultation paper and a 'Questionnaire' sheet on NICNAS website on 4 December 2012. The consultation process ran from 4 December 2012 to 25 January 2013 and a notice in regard to the consultation process was published in the Chemical Gazette of 4 December 2012, on the Australian Government Business website, and also on the Australian Government public consultation website. A reminder notice was also published in the Chemical Gazette of 2 January 2013.

The discussion paper summarised the likely impacts of NICNAS adopting the revised Sunscreen Standard 2012, and sought specific information on likely impacts on face and nail products containing sunscreen, which NICNAS was not able to estimate through its initial consultations.

The 'Questionnaire' sheet provided a list of specific queries to focus commentary from stakeholders on the likely impacts of adoption of the revised Sunscreen Standard 2012 by NICNAS. Stakeholders were asked to fill out and send the 'Questionnaire' sheet to NICNAS along with any additional comments on information not requested in the 'Questionnaire' sheet.

The period for public comments on the consultation finished at the close of business on Friday 25 January 2013.

## Results

A total of fourteen submissions were made in the form of the completed '**Questionnaire**'. Four of these were from associations representing consumers, pharmaceutical companies and retailers. A detailed analysis of results with respect to the '**Questionnaire**' is presented in the table below.

## Summary of Consultation Responses on Regulatory Impacts of NICNAS Proposal to Adopt the Revised Australian/New Zealand Sunscreen Standard 2012 for Cosmetic Sunscreen Products

Summary of views	NICNAS comments
<p><b>General information:</b> Fourteen responses were received from companies and associations representing a wide section of the mainstream cosmetic industry, and involved in activities such as importing raw material, importing sunscreens, the formulation of sunscreens; and from associations representing consumers, pharmaceutical companies and retailers. The majority of these responses were from companies and/or associations dealing with cosmetic as well therapeutic sunscreens (thirteen out of fourteen) and from companies and/or associations dealing with skin care as well as face and nail sunscreens (twelve out of fourteen).</p>	<p>NICNAS noted that responses were from a wide section of the mainstream cosmetic industry, covering the complete value-added chain, though small, cosmetic-only importers and manufacturers/formulators were not particularly represented.</p>
<p><b>Preference for option 1 (maintain status quo and do not take up the revised Sunscreen Standard 2012):</b> No responses favoured Option 1 (maintain status quo – i.e. do not adopt the revised Sunscreen Standard 2012). The main stated reasons against this option were that: the revised Sunscreen Standard 2012 provides a much greater consumer health benefit due to the improved broad spectrum requirements and a higher SPF protection; there will be lack of consistency in the application of the revised Sunscreen Standard 2012 for therapeutic and cosmetic sunscreens, as the revised Sunscreen Standard 2012 has already been adopted by the TGA, resulting in confusion among industry and consumers; and testing requirements harmonised to international standards.</p>	<p>The lack of support for Option 1 was conversely reflected by the support of all responses for Option 2 (the take up of the revised Sunscreen Standard 2012).</p>
<p><b>Preference for option 2A (adopt the revised Sunscreen Standard 2012 with a fixed transition period of 24 months, or other period)</b> Five responses were in favour of adoption of the revised Sunscreen Standard 2012 with a fixed transition period while nine responses were against this option. Of those favouring a fixed transition period, there was mixed support for shorter, two year or longer periods. The other seven responses favoured an open transition period (Option 2B).</p> <p>The main reasons in favour of taking on this option were: health benefits, consumer expectations of access to the latest cosmetic sunscreens; level playing field within the market whereby all businesses need to transition by the same end date; difficulty for consumers in discerning latest cosmetic sunscreens from old product; and the difficulty the regulator (NICNAS) will face in tracking adoption of the revised Sunscreen Standard due to there not being a requirement for registration of products.</p> <p>The main reasons against taking on this option were related to: the proposed length of the transition period (two years) being too short: high write-off costs for companies as the transition period is shorter than the normal length of the product cycle of 3-4 years for moisturisers with sunscreen and 5-7 years for tinted cosmetic products with sunscreen; and lack of consistency with the TGA's open-ended transition period.</p>	<p>NICNAS observes that: the reasons for supporting adoption of the revised Sunscreen Standard were the same reasons for lack of support for retaining the current Standard; and concerns expressed against a fixed transition period of 24 months could be addressed with a fixed but longer transition period, as well as an open-ended transition period.</p>
<p><b>Preference for Option 2B (adopt revised Sunscreen Standard 2012 with an open-ended transition period)</b> The majority of responses (nine responses) were in favour of the adoption of the revised Sunscreen Standard 2012 with an open-ended transition period while four responses were against this option.</p> <p>The main reasons were: consistency with the TGA implementation approach of the revised Sunscreen Standard 2012; consumers would drive the take up of new product; and a closed transition period of 2-4 years would not provide sufficient time for transition and would result in significant write-off costs for companies, as the usual maximum expiry date or cosmetic sunscreens is about three years and orderly clearance of stock will also take about three years.</p> <p>The main reasons against this option were: the consumer has the right to expect certainty that only products complying with the revised Sunscreen Standard will be available to consumers; that cosmetic sunscreen products will meet the same Standard as therapeutic sunscreen products; difficulty for the regulator in tracking take up of the revised Sunscreen Standard; and the lack of a level playing field amongst businesses should there be no mandated requirement for products to stop conforming to the 1998 Sunscreen Standard.</p>	<p>As with Option 2A, NICNAS observes that the reasons for supporting adoption of the revised Sunscreen Standard in Option 2B were the same reasons for lack of support for retaining the current Standard.</p> <p>As NICNAS commented in the consultation paper, the regulator will face difficulties in tracking the adoption of the revised Sunscreen Standard in an open-ended transition arrangement due to a lack of a product register.</p> <p>It is also noted that the TGA has adopted an open-ended transition period in the expectation that new product complying with the revised Sunscreen Standard will replace product complying with the 1998 Standard within a period of two-three years.</p>

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Summary of views	NICNAS comments
<p><b>Do you think that consumers will notice the stated benefits of the revised Sunscreen Standard 2012 and will prefer cosmetic sunscreen products made in compliance with that Standard?</b>                      The majority of responses (twelve of the fourteen) indicated that consumers will notice the stated benefits of the revised Sunscreen Standard 2012 and will prefer cosmetic sunscreens products made as per the revised Sunscreen Standard 2012. It was also stated that cosmetic sunscreen products, made as per the revised Sunscreen Standard 2012, provides better health protection (broad-spectrum aspect as well as higher SPF for face and nail products). It was also noted that communication in this would be a challenge for the sunscreen industry.</p>	<p>NICNAS noted in the consultation document that the revised Sunscreen Standard will impact on cosmetic products with sunscreen as follows due to the limits placed on these products by the Cosmetics Standard 2007: moisturisers with sunscreen must now comply with broad-spectrum requirements; tinted cosmetics with sunscreen can increase claimed SPF from 30+ to 50+.</p>
<p><b>Expected cost of making <u>skin care products</u> comply if the revised Sunscreen Standard 2012 is adopted by NICNAS?</b>                      The majority of responses (six responses) agreed with the expected increase in costs of skin care products in order to comply with the revised Sunscreen Standard 2012 where the products were due to be reformulated anyway. Four responses were not able to provide any comment. It was also stated that, if companies were forced to reformulate prior to the end of the product life cycle, then the absolute cost of formulation noted in the consultation document would apply, along with costs associated with the write off existing stocks. It was also noted that a greater challenge is involved in formulating new cosmetic products to comply with the revised Sunscreen Standard 2012 than anticipated in the consultation document, as formulators will need to retain the cosmetic aesthetics of the product, which will require a complete re-evaluation of the formulation.</p> <p>One response noted that as moisturisers with sunscreen under the 1998 Sunscreen Standard do not need to comply with broad-spectrum requirements whereas they must comply under the 2012 Sunscreen Standard, the business will be particularly impacted regardless of the length of a transition period, as some of its moisturiser product lines currently do not provide a broad-spectrum performance.</p>	<p>NICNAS determined likely costs of formulating products against the 1998 and 2012 Sunscreen Standard based upon information provided by industry prior to the public consultation. Based on these costs, NICNAS noted in the consultation document that there would be an increase of around \$300 in costs associated with the extra testing costs for the new broad-spectrum requirements. NICNAS also noted that the absolute cost of formulating a product against the revised Sunscreen Standard would be around \$26,000. Some respondents used this latter figure to derive a total impact on their business if all their product lines needed to be reformulated to comply against the revised Sunscreen Standard earlier than would have otherwise occurred under the normal product life cycle.</p>
<p><b>Expected costs for <u>face and nail sunscreen products</u> under different scenarios as stated if the revised Sunscreen Standard 2012 is adopted by NICNAS.</b>                      One respondent agreed with the assumption in the consultation document that the estimated cost for face and nail sunscreen products will not be significantly different from the skin care products. No respondents provided alternative cost estimates.</p>	<p>NICNAS assumed that the estimated cost for ensuring face and nail sunscreen products comply with the revised Sunscreen Standard will not be significantly different from the skin care products based on the view that the processes associated with testing and relabeling are basically similar to that for moisturiser products with sunscreen.</p>
<p><b>Will you be significantly impacted in a negative way if the revised Sunscreen Standard 2012 is adopted by NICNAS and why</b>                      The majority of responses (nine of the fourteen) indicated that they will not be impacted in a negative way if the revised Sunscreen Standard 2012 is adopted by NICNAS, while four of the responses stated that they will be impacted in a negative way. One respondent did not answer this question.</p> <p>The main reasons stated for negative responses were related to: the length of the transition period being so short as to cause products needing to be reformulated sooner than otherwise would normally occur, and if a level playing field is not achieved for cosmetic sunscreens by adoption of an open transition period whereby there will be no mandated requirement for businesses to stop complying with the 200 Sunscreen Standard.</p>	<p>NICNAS noted that negative responses were mainly associated with concerns about significant cost imposition on business resulting from a shorter fixed transition period resulting in write off and re-formulation/re-testing of existing cosmetic sunscreen products.</p>

**Summary of Consultation Responses on Regulatory Impacts of NICNAS Proposal to Adopt the Revised Australian/New Zealand Sunscreen Standard 2012 for Cosmetic Sunscreen Products**

Summary of views	NICNAS comments
<p><b>Will you be significantly impacted in a positive way if the revised Sunscreen Standard 2012 is adopted by NICNAS and why</b>                      The majority of responses (ten of the fourteen) indicated that they will be impacted in a positive way if the revised Sunscreen Standard 2012 is adopted by NICNAS, while two of the received responses stated that they will not be impacted in a positive way. Two respondents did not answer this question.</p>	<p>NICNAS noted that the main reasons for positive responses were streamlining of internal resources for cosmetics as well for therapeutic sunscreens, easier communication with consumers, greater degree of harmonisation of sunscreens and sunscreens testing nationally and globally, and better health protection for consumers.</p>
<p><b>Please provide any additional comment regarding adoption of the revised Sunscreen Standard 2012 by NICNAS.</b>                      These comments stated that the revised Sunscreen Standard 2012 is a positive move for sunscreen industry in Australia and will be a single standard defining the characteristic, performance and marking requirements for all sunscreen products supplied in the Australian market.</p>	