



Australian Government  
Department of Health and Ageing  
NICNAS

## National Industrial Chemicals Notification and Assessment Scheme

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

*Consultation on Regulatory Impacts – December 2012*

## Summary

In Australia, cosmetics are regulated by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the IC(NA) Act) 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. NICNAS is considering whether the *Cosmetics Standard 2007* should adopt the revised Sunscreen Standard 2012.

The main changes that would affect cosmetic sunscreens products on the proposed adoption of the revised Sunscreen Standard 2012 include:

- raising the maximum Sun Protection Factor (SPF) from 30+ to 50+ for face and nail products
- limiting the permitted SPF claims to 4, 6, 8, 10, 15 for skin care products and 4, 6, 8, 10, 15, 20, 25, 30, 40, 50+ for face and nail products
- making broad spectrum performance mandatory for all skin care cosmetic sunscreens and for face and nail sunscreen products with SPF 30 and above, and
- changing the criteria for categorisation of protection as low, moderate (or medium), high or very high, in accordance with the wider range of claimed SPF.

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.

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.

According to information provided by industry, the costs of development, testing and labelling of cosmetic sunscreen products (skin care) are essentially unchanged, regardless of which standard (1998 or 2012 version) the product must comply with. Moreover, unlike the TGA, NICNAS maintains neither a register of cosmetic products nor a comprehensive list of cosmetic sunscreen suppliers.

Even though there has been extensive consultation with a large number of stakeholders during the revision of the Sunscreen Standard, there may be small businesses dealing with cosmetic sunscreen products that are not members of any industry association and may not be aware of the revision of the Sunscreen Standard. These businesses may be affected by the adoption of the revised Sunscreen Standard 2012 in the *Cosmetics Standard 2007*.

Therefore, the purpose of this paper, derived from the TGA's Regulatory Impact Statement on its adoption of the revised Sunscreen Standard 2012 for therapeutic sunscreen products, is to obtain feedback on the regulatory impacts on business, community and government to inform a Government decision on the proposed adoption of the revised Sunscreen Standard (AS/NZS 2604:2012) in the *Cosmetics Standard 2007*. If adopted in the *Cosmetics Standard 2007*, the revised Sunscreen Standard 2012 would be applicable to all cosmetic sunscreen products regulated by NICNAS.

As NICNAS is currently under review by the Australian Government Department of Health and Ageing and the Department of Finance and Deregulation, the current consultation only proposes the minimum changes to the *Cosmetics Standard 2007* necessary to give full effect to the revised Sunscreen Standard 2012. Changes to the *Cosmetics Standard 2007* to modify the regulation of cosmetic products in any other way are beyond the scope of this consultation.

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## 1. Purpose of this paper

Over the past six years, Standards Australia and Standards New Zealand have been revising the Sunscreen Standard and bringing it into line with scientific developments and improvements in sunscreens and sunscreen standards applied in other developed countries. The revised Sunscreen Standard (*AS/NZS 2604:2012 Sunscreen products – Evaluation and classification*) was published on 30 May 2012. However, the NICNAS *Cosmetics Standard 2007* still requires compliance with the old Sunscreen Standard (AS/NZS 2604:1998).

The purpose of this paper is 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*. Once adopted, the revised Sunscreen Standard would be applicable to all cosmetic sunscreen products regulated by NICNAS.

There was extensive consultation with a large number of stakeholders during the revision of the Sunscreen Standard through the formation of the Joint Sunscreen Standard Committee (Committee CS-042) of Standards Australia and Standards New Zealand. Committee CS-042 was composed of representatives from a large number of Australian and New Zealand government, industry, consumer and professional organisations (Attachment 1).

Industry peak bodies have expressed a wish for NICNAS to recognise the revised Sunscreen Standard 2012 so that face, nail, and skin care cosmetic products with sunscreens that comply with the revised Sunscreen Standard 2012 may be allowed onto the Australian market.

However, there may be small businesses that are dealing with cosmetic sunscreen products, which are not aware of the revision of the Sunscreen Standard, or which are not members of any industry association, which may be affected by such a revision.

NICNAS therefore wishes to obtain the views of all stakeholders before proposing to Government whether the *Cosmetics Standard 2007* should be amended to adopt the revised Sunscreen Standard.

At the same time, the Australian Government Department of Health and Ageing and the Department of Finance and Deregulation are undertaking a review of NICNAS to investigate how the regulatory settings may be improved to enhance both the competitiveness of the Australian chemical industry and public health and environmental outcomes. In light of this Review, the current consultation only proposes the minimum changes to the *Cosmetics Standard 2007* necessary to give full effect to the revised Sunscreen Standard 2012. Changes to the *Cosmetics Standard 2007* to modify the regulation of cosmetic products in any other way are beyond the scope of this consultation.

### 1.1 What you should do ...

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

***The period for public comments on this consultation will finish at close of business on Friday 25 January 2013.***

A 'Questionnaire' sheet, which provides a list of specific queries to focus commentary from stakeholders, is available on the NICNAS website at <http://www.nicnas.gov.au/consultations.asp>.

Please fill out and send back the 'Questionnaire' sheet. You may attach additional comments if you would like to provide information not requested in the 'Questionnaire'.

Please submit the 'Questionnaire' addressed to the attention of Dr Harjit Deol by:

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## 2. Background to the consultation

### 2.1 Importance of sunscreens

Overexposure to the ultraviolet (UV) radiation emitted by the sun can cause significant damage to exposed and unprotected human skin, resulting in sunburn in the short term and skin cancers (melanoma and non-melanoma) in the longer term. The actual damage that leads to these effects may occur many years before these effects actually appear. Australia and New Zealand have the highest rates of skin cancer in the world. According to information published by the Australian Bureau of Statistics, the Australian Institute of Health and Welfare (AIHW), and the Cancer Council of Australia, about 10,300 cases of melanoma and about 434,000 cases of non-melanoma are diagnosed and treated annually in Australia.

The use of primary sunscreens is one of the five recommended measures to reduce the risk of sun damage and skin cancer, in combination with other measures, namely: sun-protective clothing, a hat, sunglasses, and keeping to the shade as much as possible.

Many Australians also use cosmetics, lipsticks, lip balms, and nail products containing sunscreens every day of their lives. Whilst these products should not be used instead of primary sunscreens when the desired result is to protect against sunburn and skin cancer, nonetheless, cosmetic sunscreens also do provide a sun protection benefit in addition to their primary cosmetic role. It is therefore important that these products are safe, effective and that consumers have access to the latest sunscreen innovations in these products.

The portion of the sun's UV spectrum with wavelengths in the range 290-320 nanometres is known as "UVB" and is mainly responsible for sunburn. Sunburn is painful but normally fades away or the burned skin peels off within a few days.

The portion of the sun's UV spectrum with wavelengths in the range 320 to 400 nanometres is known as "UVA". This penetrates deeper into the skin than UVB radiation and is considered to be mainly responsible for the longer term damage resulting in melanomas, other skin cancers and other effects on skin. If not removed in time, melanomas and other skin cancers can lead to serious disfigurement or death.

### 2.2 The sunscreen market in Australia

Based on the 26 weeks of sales data up to 3 June 2012 provided by industry, annual sales of cosmetic sunscreen (facial moisturiser) products in Australia amounted to 1.1 million units. About 0.85 million units of these products were sold through grocery outlets and about 0.25 million units were sold through pharmacies. NICNAS does not have comparable data for the sale of face and nail products.

As a comparison, annual sales of therapeutic (primary) sunscreens in Australia amounted to 6.6 million units. About 4.4 million units were sold through grocery outlets and about 2.2 million units were sold through pharmacies. This indicates that, as a comparison with the primary sunscreens, the cosmetic sunscreens market is small (about 1/6 the size).

### 2.3 Regulation of sunscreens in Australia

In Australia, sunscreens fall into two categories based on their function (and also based on how they are regulated): "primary sunscreens" (also known as "therapeutic sunscreens") and "secondary sunscreens" (which cover both "cosmetic sunscreens" and some "therapeutic sunscreens"), as follows:

- primary sunscreens (those used primarily for protection of all parts of the body from UV radiation from sunlight) are regulated as low-risk medicines by the TGA and must be listed in the ARTG.
- secondary sunscreens (products that contain sunscreens agents but whose primary purpose is something other than sunscreens) may, depending on their nature and SPF rating, be classified and regulated as medicines (in the same way as primary sunscreens) or be classified

as cosmetics in accordance with the *Cosmetics Standard 2007* and regulated by NICNAS and the Australian Competition and Consumer Commission (ACCC).

Secondary sunscreens regulated by the TGA as medicines include moisturisers with sunscreen having an SPF greater than 15.

Secondary sunscreens regulated as cosmetics by NICNAS and the ACCC include:

- moisturisers with sunscreen with SPF up to 15
- sunbathing products (eg oils, creams or gels, including products for tanning without sun and after sun care products) with SPF between 4 and 15
- make-up products with sunscreens, and
- lip-sticks and lip balms with sunscreens.

Cosmetic sunscreens must comply with the *Industrial Chemicals (Notification and Assessment) Act 1989* (the IC(NA) Act), the *Industrial Chemicals (Notification and Assessment) Regulations 1990*, the *Cosmetics Standard 2007* and with the relevant sections of the Sunscreen Standard (AS/NZS 2604:1998). Their labelling must also comply with the cosmetics legislation, including the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991*. The requirements for cosmetic sunscreens are summarised in the *NICNAS Cosmetic Guidelines*. The requirements and differences between “Cosmetic Sunscreens” and “Therapeutic Sunscreens” are summarised in Attachment 2.

## **2.4 References to the Sunscreen Standard in the *Cosmetics Standard 2007***

A cosmetic of a product category and type mentioned in an item of Schedule 1 of the *Cosmetics Standard 2007* must comply with the relevant sections of the Australian and New Zealand Sunscreen Standard (AS/NZS 2604:1998).

The Sunscreen Standard 1998 (AS/NZS 2604:1998) is currently referenced as a ‘standard’ for face and nail, and for skin care products categories in the *Cosmetics Standard 2007*. Although the Sunscreen Standard has been revised a number of times in the past 20 years to raise the level of sun protection, as the *Cosmetics Standard 2007* was created in 2007, this is the first time that the Sunscreen Standard has been revised since it has been managed within the NICNAS regulatory context (Attachment 3).

## **2.5 Need for revision of the Sunscreen Standard 1998**

The Sunscreen Standard was first published in 1983 and was revised in 1986, 1993, 1997, 1998, and 2012 (Attachment 4). The previous Sunscreen Standard (AS/NZS 2604:1998) is currently referenced by the *Cosmetics Standard 2007*.

There has been significant development in sunscreen technology over the years and, overseas, consumers are already able to purchase sunscreens with much higher SPF ratings than 30+, which also provide more protection from UVA radiation.

Maintaining the old Sunscreen Standard 1998 has also created a potential trade barrier by preventing the import of products with improved broad spectrum performance (skin care products) and higher-SPF products (lip and nail products) to Australia. It has also limited the ability of Australian manufacturers to market these products in both Australia and overseas.

Consequently, requiring adherence to the old Sunscreen Standard 1998 means that Australia has lagged behind the rest of the world in terms of access by the public to the most effective and beneficial cosmetic sunscreen products for face and nail and for skin care. This has been recognised by the sunscreen industry in Australia and has been a secondary stimulus for updating of the Sunscreen Standard, the primary stimulus being in relation to its adoption for therapeutic sunscreens.

## 2.6 The revised Sunscreen Standard (AS/NZS 2604:2012)

Over the past six years, Standards Australia and Standards New Zealand, the organisations responsible for the Standard, have been revising the Sunscreen Standard and bringing it into line with scientific developments and improvements in sunscreens and sunscreen standards applied in other developed countries.

The revised Sunscreen Standard (AS/NZS 2604:2012) was published on 30 May 2012 by Standards Australia and Standards New Zealand. However, the *Cosmetic Standard 2007* still requires compliance with the old Sunscreen Standard (AS/NZS 2604:1998). In the meantime, the TGA adopted the revised Sunscreen Standard 2012 for therapeutic sunscreens in November 2012 (see section 2.8).

The following are the main changes in the revised Sunscreen Standard 2012 as compared with the old Sunscreen Standard 1998. Details of these changes are provided in Attachment 4:

- Raising the maximum SPF that may be claimed on the label of a sunscreen product from 30+ to 50+, limiting the permitted SPF claims to 4, 6, 8, 10, 15, 20, 25, 30, 40, 50 and 50+ (depending on the SPF test result) and removing the claim of SPF 30+.
- Raising the minimum claimable SPF from 2 to 4. This will affect all cosmetic sunscreen products.
- Changing the criteria for categorisation of protection as 'low', 'medium' (or 'moderate'), 'high' or 'very high' in accordance with the wider range of SPF claims allowed, as tabulated below. This affects all cosmetic sunscreen products.

Protection category	Old Standard	Revised Standard
Low	SPF 4—7	SPF 4, 6, 8, 10
Moderate (or medium)	SPF 8—14	SPF 15, 20, 25
High	SPF 15—29	SPF 30, 40, 50
Very high	SPF 30 or more	SPF 50+

- Making broad spectrum performance mandatory for all skin care cosmetic sunscreens, and for face and nail sunscreen products with SPF of 30 and above.

The current Sunscreen Standard requires all sunscreens labelled with an SPF greater than 15 to provide broad spectrum protection. However, the revised Sunscreen Standard 2012 would make broad spectrum protection mandatory for all skin care products with sunscreen that are regulated by NICNAS (with SPF 4<15).

- Adoption of the test procedure in the International Standard ISO 24443:2012 for determining broad spectrum performance. This procedure requires the degree of protection from UVA to increase with increasing SPF and is significantly more stringent than the broad spectrum test procedure in AS/NZS 2604:1998. A typical SPF 50+ sunscreen complying with the revised Sunscreen Standard 2012 would provide 10 - 20 times the protection against UVA radiation provided by a typical SPF 30+ sunscreen complying with the old Sunscreen Standard 1998.

As minimum mandatory required level of UVA may already be present in skin care cosmetic sunscreen products and therefore, this may not be relevant to cosmetic skin care products as the SPF level of these products is limited to SPF15 by the *Cosmetics Standard 2007*, this requirement does specify the minimum level of protection against UVA radiation needed to be provided by cosmetic sunscreens. However, this is relevant to face and nail products as there is no specified limit on claimed SPF level for these products as long as it is within the specified revised Sunscreen Standard 2012.

- The water resistant aspect of the revised Sunscreen Standard 2012 does not apply to the skin care products regulated by NICNAS. However, this could apply to face and nail products as these are allowed to make a claim for water resistance.
- Some other changes to the revised Sunscreen Standard 2012 are further discussed at Attachment 4.

These effects of these changes in the Sunscreen Standard on specific cosmetic sunscreen product categories are summarised in the table below.

Product Category	Labelled Sun Protection Factor	Broad-Spectrum	Labelling Requirements	Water Resistant
Face and Nail	The labelled sun protection factor for these products has now been increased to 50+ (for 60 or higher SPF), as compared to 30+ (for SPF 30 or more) in the old Sunscreen Standard.  The claimed category description is affected.	This is affected as broad-spectrum performance requirement is now compulsory for these products with labelled sun protection factor of 30 and above, as compared to the labelled sun protection factor of 15 or above in the old Sunscreen Standard.	There are new (conditional) labelling requirements for these products.	This is affected as water resistant claims are allowed with sun protection factor of 8 or above for these products, as compared to the sun protection factor of 4 or above in the old Sunscreen Standard.
Skin care	The maximum permitted SPF for these products has not changed, as compared to the old Sunscreen Standard. However, labelled SPF claim is better defined as 4, 6, 8, 10, and 15.  The claimed category description is affected.	This is affected as all skin care cosmetic sunscreen products now must meet the performance requirements for broad-spectrum products.	There are new (conditional) labelling requirements for these products.	Not affected as water resistant claim is not allowed for skin care cosmetic sunscreen products.

## 2.7 Expected amendments to the *Cosmetics Standard 2007* following adoption of the revised Sunscreen Standard 2012 by NICNAS and its main effects on cosmetic sunscreen products:

Amendments to the *Cosmetics Standard 2007* following the possible adoption of the revised Sunscreen Standard 2012 by NICNAS would include the following (see Attachment 3 for current requirements for cosmetic sunscreen products in *the Cosmetics Standard 2007*):

- The references to the old Sunscreen Standard (AS/NZS 2604:1998) will be replaced with references to the revised Sunscreen Standard (AS/NZS 2604:2012).
- For Face and Nail product categories:
  - any protection factor or equivalent category description stated on the product's label must be in accordance with clauses 5 and 6 of AS/NZS 2604:2012
  - the product must meet the performance requirements for a broad-spectrum product set out in clauses 5.2 and 6.3 of AS/NZS 2604:2012, and
  - if the product's label states a protection factor, the label must meet the requirements of clauses 7.1 and 7.3 of AS/NZS 2604:2012.

- For Skin Care product categories:
  - the product must meet the performance requirements for a broad-spectrum product set out in clauses 5.2 and 6.3 of AS/NZS 2604:2012
  - any protection factor or equivalent category description stated on the product's label must be in accordance with clauses 5 and 6 of AS/NZS 2604:2012, and
  - if the product's label states a protection factor, the label must meet the requirements of clauses 7.1 and 7.3 of AS/NZS 2604:2012.

## **2.8 Adoption of the Revised Sunscreen Standard 2012 by the TGA**

Primary sunscreens (those used primarily for protection of all parts of the body from UV radiation from sunlight) are regulated as low-risk medicines by the TGA and must be listed in the ARTG.

As of 13 November 2012, the *Therapeutic Goods Regulation* 1990 has been amended to recognise the revised Sunscreen Standard (AS/NZS 2604:2012) as the legal requirement for new sunscreens entering the ARTG. Sunscreens currently listed in the ARTG, complying with the old Sunscreen Standard (AS/NZS 2604:1998), may remain listed.

Allowing sunscreens that comply with the old Sunscreen Standard (AS/NZS 2604:1998), and were listed in the ARTG prior to the amendments coming into force, to remain listed and available in the Australian market, avoids major disruption of the supply of sunscreens in Australia or write-off of existing stock. It also allows manufacturers and sponsors time to bring their product ranges into line with the new Standard.

## **2.9 Understanding the different stakeholders for therapeutic and cosmetic sunscreens**

NICNAS does not maintain a register of cosmetic products. While businesses that introduce (import or manufacture) chemicals in Australia must register with NICNAS, cosmetic manufacturers that source their chemicals domestically may not need to register with NICNAS if they are not introducers under the requirements of the *IC(NA) Act*. Some businesses supply both therapeutic and cosmetic products whilst others do not.

While there could be efficiency gains for a business that deals with both TGA and NICNAS if NICNAS were also to adopt the revised Sunscreen Standard 2012, NICNAS wishes to understand the views of all businesses that may be affected by any proposed adoption of the revised Sunscreen Standard 2012 for cosmetic products.

### 3. Options available to NICNAS

There are two possible options available to NICNAS regarding adoption of the revised Sunscreen Standard 2012 in the *Cosmetics Standard 2007*:

#### **Option 1: Maintain *status quo* and not amend the *Cosmetics Standard 2007* to adopt the revised Sunscreen Standard 2012**

Maintaining the status quo in Australia would have the following consequences:

- There will be a lack of consistency of application of the Sunscreen Standard with respect to therapeutic and cosmetic sunscreen products. As a result of this, businesses and consumers would need to relate to two different versions of the Sunscreen Standard, resulting in inefficiencies for business and confusion among consumers.
- The revised Sunscreen Standard 2012 prescribes more stringent requirements for “broad spectrum” protection from UVA radiation (applicable to all cosmetic sunscreen products, though optional for face and nail with SPF less than 30), compared with the old Sunscreen Standard 1998. Therefore, there would be little point in companies trying to market in Australia cosmetic sunscreens with the higher protection against UVA radiation required by the revised Sunscreen Standard 2012, and consumers would not benefit from these products.
- The additional protection against UV radiation delivered by very high SPF broad spectrum face and nail sunscreen products would not be available to Australian consumers and in the long term, this could mean that some consumers could eventually develop sun related skin effects that could otherwise be prevented.
- In New Zealand, it is already possible to market cosmetic sunscreens that comply with the revised Sunscreen Standard 2012. As compared to their New Zealand counterparts, Australian consumers would be denied the availability of such cosmetic sunscreens.

#### **Option 2: Adopt the revised Sunscreen Standard 2012**

If the revised Sunscreen Standard 2012 were adopted in the *Cosmetics Standard 2007*, NICNAS would make only the minimum regulatory changes needed to give effect to the revised Sunscreen Standard 2012 whilst maintaining the current scope of the *Cosmetics Standard 2007*.

Adopting this option would mean that new cosmetic sunscreen products with improved broad spectrum performance (applicable to all cosmetic sunscreen products, though optional for face and nail with SPF less than 30) and higher SPF claims up to 50+ (face and nail products only) could lawfully enter the Australian market and be available for consumers. Industry has noted that many cosmetic sunscreen products (skin care) currently in Australia already comply with the performance requirements of the revised Sunscreen Standard 2012 (reflecting the supply available overseas) and so reformulation would not be necessary. However, product re-labelling would be required in these instances.

This option could have two further sub-options relating to transitional arrangements. Similarly to the TGA, NICNAS does not wish to unduly impact businesses by requiring the immediate mandatory adoption of the revised sunscreen product, with the consequent write-offs of existing stock or reformulation of existing products that comply with the 2008 Sunscreen Standard but not the 2012 Sunscreen Standard. The TGA has adopted an open-ended transitional approach whereby existing therapeutic sunscreens can remain on the ARTG indefinitely, in the expectation that the market will drive their replacement within around 24 months as was the case with previous revisions of the Sunscreen Standard. Presumably, this replacement will also be driven by consumers who will be able to see via labelling that a new product has a higher SPF (up to 50+ compared to old product of 30+ for face and nail products) or enhanced broad spectrum performance (for all cosmetic sunscreen products, though optional in some instances).

However, for cosmetic sunscreen products, as noted above, NICNAS does not maintain a register of products. Moreover, for skin care products with SPF which are limited by the *Cosmetics Standard 2007* to SPF of no more than 15 (though improved broad spectrum performance is mandatory), consumers may not be able to perceive a clear benefit pertaining to products complying with the revised Sunscreen Standard 2012, particularly as these products are not designed to be a primary protection against skin cancer caused by sun damage. Therefore, a market-driven changeover may not be the most efficient way in which to drive the replacement of old product by new. Hence, NICNAS proposes two sub-options for possible transitional arrangements as follows:

**Option 2A: Adopt the revised Sunscreen Standard 2012 and allow currently marketed cosmetic sunscreen products to remain in the market for another 24 months**

In this option, manufacturers would have a finite period of time (24 months) within which they must replace existing products that do not conform to the revised Sunscreen Standard 2012 with product that does. The 24 month period is proposed on the basis that this is taken to be the maximum turnaround time of product in what is a fast-moving market.

**Option 2B: Adopt the revised Sunscreen Standard 2012 and allow currently marketed cosmetic sunscreen products complying with the old Sunscreen Standard 1998 to remain available on the Australian market indefinitely**

In this option, there would be no mandatory period within which manufacturers must replace old product with new product. This option is similar to the TGA option and a market-driven transition period is expected. This option is predicated on whether it is reasonable to expect that market forces and other commercial considerations will lead manufacturer and sponsors to discontinue marketing of their cosmetic sunscreen products complying with the old Sunscreen Standard 1998 within a few years of adoption of the revised Sunscreen Standard 2012 in the *Cosmetics Standard 2007*, thereby delivering benefits to consumers and efficiencies to business in a reasonable timeframe.

Note that cosmetic sunscreens products complying with the old Sunscreen Standard 1998 still provide good protection from UV radiation and are not unsafe, even though these products may not be as protective as products complying with the revised Sunscreen Standard 2012.

## 4. Regulatory Impact Analysis of available options

### 4.1 Impacts of Option 1 (maintain *status quo* and not amend the *Cosmetics Standard 2007* to adopt the revised Sunscreen Standard 2012)

If the status quo is maintained and NICNAS does not take up the revised Sunscreen Standard 2012, it will have the following main impact on different stakeholders:

#### Businesses:

- As the TGA has adopted the revised Sunscreen Standard 2012, there will be lack of consistency across therapeutic (regulated by the TGA) and cosmetic sunscreen (regulated by NICNAS) products. This would result in business confusion and inefficiency for the sunscreen industry as some companies may be involved in marketing both therapeutic as well as cosmetic sunscreens products and these companies would have to deal with two Sunscreen Standards in Australia at the one time.
- Although Australian manufacturers will still be able to export cosmetic sunscreen product complying with the revised Sunscreen Standard 2012 to overseas markets, it may be cost inhibitory as these companies will need to work with two systems of Sunscreen Standards (the 2012 Sunscreen Standard in relation to exports, and the 2008 Sunscreen Standard in relation to domestic sales). This is similar to the case for foreign manufacturers, and so the Australian market might become increasingly less attractive to them.

#### Community:

- Consumers may be denied access to higher-performing cosmetic sunscreen products, which would include improved sun protection afforded by the imposition of more stringent broad spectrum requirements across all cosmetic sunscreen products (though optional for face and nail products with SPF less than 30), and increased maximum claimed SPF from 30+ to 50+ for face and nail products.

There may also be confusion among consumers regarding the protection afforded by cosmetic sunscreen products because the claims allowed on product labels regarding the SPF rating and the description of the amount of protection provided, will be inconsistent.

#### Government:

- NICNAS would avoid the need to manage transitional and compliance arrangements. However, it would need to educate businesses and consumers seeking to clarify whether a sunscreen product is regulated by NICNAS or the TGA, and thus which Sunscreen Standard would apply.
- The ACCC would not be expected to be impacted by this option as it currently administers ingredient labelling requirements rather than performance labelling requirements, and ingredient labelling is not affected by the Sunscreen Standard.

### 4.2 Impacts of Option 2 (adopt the revised Sunscreen Standard 2012)

#### Option 2A: Adopt revised Sunscreen Standard 2012 and also allow currently marketed cosmetic sunscreen products to remain in the markets for another 24 months

#### Businesses:

If NICNAS does take up this option, it will have the following main impacts:

- Cosmetic sunscreen products (face, nail and skin care products) currently under NICNAS regulation and complying in all respects with the old Sunscreen Standard 1998, could remain available on the Australian market for another 24 months. This would avoid any major disruption to the availability of skin care, face and nail products with which consumers are currently familiar, and could also avoid any potential write-offs of existing stock.

- Australian manufacturers will be able to develop and market sunscreen products both in Australia and overseas that comply with the revised Sunscreen Standard 2012, and achieve economies of scale. Similarly, foreign manufacturers are likely to have already developed products complying with the revised Sunscreen Standard 2012 for markets outside Australia and they would then be able to export them to Australia without having to face the financial burden of developing and producing Australian-specific formulations as they do now. They would also benefit from the economies of scale that flow from having a larger market for their products.
- Businesses trading in both cosmetic and therapeutic sunscreen products, who deal with two different regulators, would only need to understand one Sunscreen Standard.
- According to information provided by the sunscreen industry, the costs of development, testing and labelling of cosmetic sunscreen products (skin care) are essentially the same regardless of which standard (1998 or 2012 version) the product must comply with (see next section).

#### **Community:**

The benefits to consumers accessing higher-performing cosmetic sunscreen products, complying with the revised Sunscreen Standard 2012 include:

- improvement in sun protection afforded by the imposition of more stringent broad spectrum requirements (the ability to protect against both the cancer-causing and sunburn-causing effects of UV light) across all cosmetic sunscreen products (optional for face and nail products with SPF less than 30), and by raising the maximum claimed SPF from 30+ to 50+ for face and nail products; and
- improved consumer understanding of the protection afforded by cosmetic sunscreen products by clarifying the claims allowed on product labels regarding the SPF rating and the description of the amount of protection provided.

#### **Government:**

- There will be some additional cost to NICNAS (funded by industry under cost recovery arrangements) during the 24-month transitional period for maintaining two versions of the Sunscreen Standard concurrently, and monitoring compliance with the changeover at the end of the transition period.

#### **Option 2B: Adopt revised Sunscreen Standard 2012 and allow current cosmetic sunscreen products which comply with the old Sunscreen Standard 1998 to remain available on the Australian market indefinitely**

It is reasonable to assume that the marketability of cosmetic sunscreen products complying with the old Sunscreen Standard 1998 would decline as products complying with the revised Sunscreen Standard 2012 become available. However this may be driven by supply considerations (as the supply of imported product complying with the 2008 Sunscreen Standard dries up) rather than demand considerations (as consumers may not discern a clear benefit of purchasing cosmetic sunscreen products complying with the revised Sunscreen Standard 2012). Therefore, although it is expected that the availability of cosmetic sunscreen products made as per the old Sunscreen Standard 1998 will start declining soon after the adoption of the revised Sunscreen Standard 2012, it is uncertain when these old products will completely disappear from the shelves.

#### **Business, Community and Government:**

Compared to Option 2A with a defined transition period of 24 months, the indefinite transition period in Option 2B would have the additional impacts of potentially increasing the period in which both the 2008 and 2012 versions of the Sunscreen Standard are in force. This would therefore increase the period of potential confusion for consumers (to the extent they could discern a difference between old and new products), inefficiencies for government (in administering both versions of the Sunscreen Standards) but possibly less impact on industry (in as much as they are free to determine how long they wish to transition for compared to an enforced 24 months period).

### 4.3 Impact of Option 2 on costs for industry following adoption of the revised Sunscreen Standard 2012 by NICNAS for skin care products with SPF 15

Based on the information provided by industry, the estimated costs relating to the adoption of the revised Sunscreen Standard (AS/NZS 2604:2012), as compared with the old Sunscreen Standard (AS/NZS 2604:1998), for a cosmetic sunscreen product (skin care) with SPF 15 under different scenarios, are indicated as below:

#### Scenario 1: Introduction of a new cosmetic sunscreen product (skin care) into Australia, under the revised Sunscreen Standard 2012

Under this scenario, companies are developing, testing and labelling a completely new cosmetic sunscreen (skin care) product with a SPF 15, complying with the revised Sunscreen Standard 2012. The additional cost to industry would be about \$300 in once-off costs.

Tests		Associated costs under:	
		old Standard	revised Standard
<b>Efficacy</b>	<i>In Vivo</i> SPF Test (static) 15	\$1,880	\$1,880
	<i>In Vitro</i> Broad Spectrum Test	\$295	\$595
	Water Resistance Test	N/A	N/A
	<b>Total</b>	<b>\$2,175</b>	<b>\$2,475</b>
<b>Formulation</b>	Formulation	\$5,000	\$5,000
	<b>Total</b>	<b>\$5,000</b>	<b>\$5,000</b>
<b>Stability</b>	Stability Testing	\$7,000	\$7,000
	Analytical Validation	\$9,000	\$9,000
	<b>Total</b>	<b>\$16,000</b>	<b>\$16,000</b>
<b>Label changes</b>	Artwork	\$500	\$500
	On Pack Printing Screens	\$500	\$500
	Carton Printing Plates	\$2,000	\$2,000
	<b>Total</b>	<b>\$3,000</b>	<b>\$3,000</b>
<b>Total</b>		<b>\$26,175</b>	<b>\$26,475</b>

The above table does not include costs for any toxicity tests as these would be same for the old and the revised Sunscreen Standard 2012 and therefore are not relevant for the present discussion.

#### Scenario 2: Re-marketing of an existing cosmetic sunscreen (skin care) product into Australia under the revised Sunscreen Standard 2012, without any formulation change

This scenario assumes the reasonable case (based on industry information) that some current cosmetic sunscreen (skin care) products will be able to meet the requirements of the revised Sunscreen Standard 2012 without any change in the formulation. It is also assumes that companies will be able to sell their old stock with a updated labels complying with the revised Sunscreen Standard 2012 or use the same old formulation to repack with new labels complying with the revised Sunscreen Standard 2012. The additional cost to industry would be about \$300 in once-off costs.

**Scenario 2:**

Tests		Associated costs under:	
		old Standard	revised Standard
<b>Efficacy</b>	<i>In Vivo</i> SPF Test (static) 15	\$1,880	\$1,880
	<i>In Vitro</i> Broad Spectrum Test	\$295	\$595
	Water Resistance Test	N/A	N/A
	<b>Total</b>	<b>\$2,175</b>	<b>\$2,475</b>
<b>Label changes</b>	Artwork	\$500	\$500
	On Pack Printing Screens	\$500	\$500
	Carton Printing Plates	\$2,000	\$2,000
	<b>Total</b>	<b>\$3,000</b>	<b>\$3,000</b>
	<b>Total</b>	<b>\$5,175</b>	<b>\$5,475</b>

**Scenario 3: Re-marketing of an existing cosmetic sunscreen (skin care) product into Australia under the revised Sunscreen Standard 2012, with a change in the formulation**

This scenario assumes that some current cosmetic sunscreen (skin care) products do not comply with the revised Sunscreen Standard 2012 and these products will be marketed with a change in formulation and other testings, to comply with the revised Sunscreen Standard 2012. However, advice from industry notes that such reformulation would be no more expensive than formulating against the 2008 Sunscreen Standard. The additional cost to industry would be about \$300 in once-off costs.

Tests		Associated costs under:	
		old Standard	revised Standard
<b>Efficacy</b>	<i>In Vivo</i> SPF Test (static) 15	\$1,880	\$1,880
	<i>In Vitro</i> Broad Spectrum Test	\$295	\$595
	Water Resistance Test	N/A	N/A
	<b>Total</b>	<b>\$2,175</b>	<b>\$2,475</b>
<b>Formulation</b>	Formulation	\$5,000	\$5,000
	<b>Total</b>	<b>\$5,000</b>	<b>\$5,000</b>
<b>Stability</b>	Stability Testing	\$7,000	\$7,000
	Analytical Validation	\$9,000	\$9,000
	<b>Total</b>	<b>\$16,000</b>	<b>\$16,000</b>
<b>Label changes</b>	Artwork	\$500	\$500
	On Pack Printing Screens	\$500	\$500
	Carton Printing Plates	\$2,000	\$2,000
	<b>Total</b>	<b>\$3,000</b>	<b>\$3,000</b>
	<b>Total</b>	<b>\$26,175</b>	<b>\$26,475</b>

## **Overall impact of Option 2 on costs for industry concerned with skin care product, following adoption of the revised Sunscreen Standard 2012 by NICNAS**

The scenarios indicate the following points:

- The main cost associated in uptake of the revised Sunscreen Standard 2012 is adoption of the test procedure in the International Standard (ISO 24443:2012) for determining broad spectrum performance. This procedure requires the degree of protection from UVA to increase with increasing SPF and is significantly more stringent than the broad spectrum test procedure in the old Sunscreen Standard (AS/NZS 2604:1998).
- The additional cost for the industry would be around \$500 to accommodate the mandatory requirement of broad spectrum performance of cosmetic sunscreen (skin care) products. However, this additional cost would be around \$300 if the company was already conducting a broad spectrum test for better marketing.
- It is expected that most of the current formulations of cosmetic sunscreen (skin care) products would meet the more stringent requirements of broad spectrum performance. However, it is also possible this may not be the case and that companies may need to change formulation to meet new broad spectrum requirement. The advice from industry notes that such reformulation would be no more expensive than formulating against the 2008 Sunscreen Standard. The additional cost to industry would be about \$300 in once-off costs.

### **4.4 Overall impact of Option 2**

As outlined above, adoption of the revised Sunscreen Standard 2012 would result in some one-off costs for industry and possibly ongoing increased prices faced by consumers. On the other hand, the benefits to the public would be the availability of clearly identifiable cosmetic sunscreen products with better protective properties that could reduce the skin related effects due to UV radiation. There will also be consistency with the TGA and other developed countries in the adoption of the revised Sunscreen Standard 2012. Finally, businesses that deal with both therapeutic and cosmetic sunscreen products, and therefore interact with two regulators (NICNAS and the TGA) will face only incremental costs in adapting to the revised Sunscreen Standard 2012 in regard to cosmetic sunscreen products as they will have already adapted to the revised Sunscreen Standard 2012 implemented by the TGA for therapeutic sunscreen products in November 2012.

## 5. NICNAS-preferred option

Based on the information available to NICNAS to date, and pending any further information from stakeholders on the likely impacts of the above options, NICNAS prefers Option 2A of adopting the revised Sunscreen Standard 2012 with a closed 24-month transitional period.

This is on the basis that Option 2A provides the greatest net benefit to community due to:

- the provision of higher-performing (especially regarding broad spectrum requirements) cosmetic sunscreen products to consumers, noting these products are secondary sunscreens and are therefore not primarily designed to provide protection against the sun;
- positive impacts on industry arising from the take-up of the revised Sunscreen Standard 2012 by NICNAS in the context of the TGA already having adopted the revised Sunscreen Standard 2012 for therapeutic products.
- a defined impact on government whereby NICNAS will need to manage compliance against two versions of the Sunscreen Standard for a defined, as opposed to possibly indefinite, period of time.

## 6. Future steps

Following on from this regulatory impact analysis, if a decision is made by Government not to adopt the revised Sunscreen Standard (AS/NZS 2604:2012), nothing will change and the *Cosmetics Standard 2007* will continue to reference the old Sunscreen Standard (AS/NZS 2604:1998).

However, if a decision is made by Government to adopt the revised Sunscreen Standard (AS/NZS 2604:2012), a process will be initiated to amend the *Cosmetics Standard 2007* to recognise the revised Sunscreen Standard 2012. The amended *Cosmetics Standard 2007* will be registered on the Federal Register of Legislative Instruments and published through NICNAS's website. NICNAS also intends that the amendments commence immediately. NICNAS will then need to instigate compliance oversight to ensure the appropriate changeover of cosmetic sunscreen products to the revised Sunscreen Standard 2012 within the designated transition period, and will seek the assistance of stakeholders in promulgating these changes throughout the market.

## Attachment 1: Composition of Committee CS-042

Committee CS-042 was formed for the revision of old Sunscreen Standard (1998 version) and composed of representatives from the following large number of relevant Australian and New Zealand Government, industry, consumer and professional organisations:

1. Accord Australasia
2. Australasian College of Dermatologists
3. Australasian Faculty of Occupational and Environmental Medicine
4. Australian Chamber of Commerce and Industry
5. Australian Food and Grocery Council
6. Australian Radiation Protection and Nuclear Safety Agency
7. Australian Self Medication Industry (ASMI)
8. Australian Society of Cosmetic Chemists
9. Cancer Society of New Zealand
10. Consumers Federation of Australia
11. Cosmetic, Toiletry and Fragrance Association of New Zealand
12. Measurement Standards Laboratory of New Zealand
13. Medicines Australia
14. National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
15. New Zealand Employers and Manufacturers Association (Central)
16. Testing Interests, Australia (both Dermatest and the APTF)
17. The Cancer Council, Australia
18. Therapeutic Goods Administration (TGA)
19. University of Sydney

This Committee also provided delegates to, and substantial input into, the International Standards Organisation (ISO) discussions on the development and finalisation of the ISO Standards ISO 24443 – *In vitro determination of UVA protection* (the test procedure for determining broad spectrum performance) and ISO 2444 – *In vivo determination of SPF* (the test procedure for determining the SPF of sunscreens). These two ISO Standards are referenced in ASD/NZS 2604:2012 and replace the corresponding test procedures in AS/NZS 2604:1998.

## Attachment 2: Regulatory requirements for Cosmetic Sunscreens and Therapeutic Sunscreens

Cosmetic Sunscreens	Therapeutic Sunscreens
Regulated by NICNAS and the ACCC	Regulated by the TGA
<p>Includes:</p> <p>Secondary Sunscreens that are “Cosmetics” according to the <i>IC(NA) Act</i> and the <i>Cosmetics Standard 2007</i>, namely:</p> <ul style="list-style-type: none"> <li>- Moisturisers with sunscreen if SPF is 15 or less</li> <li>- Sunbathing products with SPF between 4 and 15</li> <li>- Lip balms/lip sticks with sunscreen</li> <li>- “Make-up” products with sunscreen</li> </ul>	<p>Includes:</p> <p>All “Primary Sunscreens”</p> <p>“Secondary Sunscreens” that do not meet the requirements of the <i>IC(NA) Act</i> and the <i>Cosmetics Standard 2007</i>. [These are mainly moisturizers with sunscreen with SPF greater than 15]</p>
<p>Requirements:</p> <ul style="list-style-type: none"> <li>• Must comply with the <i>IC(NA) Act</i> and the <i>Cosmetics Standard 2007</i> which includes references to AS/NZS 2604:1998</li> <li>• Labelling must comply with the relevant consumer and cosmetics legislation</li> <li>• Not required to be registered or listed in a database maintained by a regulatory authority</li> </ul>	<p>Requirements :</p> <ul style="list-style-type: none"> <li>• Must comply with AS/NZS 2604:2012</li> <li>• Labelling must comply with Sunscreen Standard and the Labelling Order TGO 69</li> <li>• Manufacture must comply with the Code of Good Manufacturing Practice</li> <li>• Must be formulated using ingredients approved by the TGA</li> <li>• Must be “listed” or “registered” in the ARTG</li> </ul> <p>Companies pay application fees for listing/registration and annual charges</p>

### Attachment 3: References to the Sunscreen Standard in the *Cosmetics Standard 2007*

The old Sunscreen Standard (AS/NZS 2604:1998) is referred to in the *Cosmetics Standard 2007* for face and nail and for skin care products, as follows:

#### Schedule 1 Standards (section 4)

Item	Product category	Product type	Standards
1	Face and nail	<p>1.1 Tinted bases or foundation (liquids, pastes or powders) with sunscreen</p> <p>1.2 Products intended for application to the lips with sunscreen</p>	<p>Both:</p> <p>(a) the product must be a secondary sunscreen product within the definition of <b><i>secondary sunscreen product</i></b> in <b>AS/NZS 2604:1998</b>; and</p> <p>(b) any protection factor or equivalent category description stated on the product's label must be in accordance with clauses 6.2 and 6.3 of <b>AS/NZS 2604:1998</b></p>
2	Skin care	<p>1.1 Moisturising products with sunscreen for dermal application, including anti-wrinkle, anti-ageing and skin whitening products</p> <p>1.2 Sunbathing products (eg oils, creams or gels, including products for tanning without sun and after sun care products) with a sun protection factor of at least 4 and not more than 15</p>	<p>All of the following:</p> <p>(a) the product must be a secondary sunscreen product within the definition of <b><i>secondary sunscreen product</i></b> in <b>AS/NZS 2604:1998</b>;</p> <p>(i) not be presented as having a sun protection factor of more than 15; and</p> <p>(ii) not be presented as water-resistant; and</p> <p>(iii) if it is not stable for at least 36 months — include an expiry date or use-by date on its label; and</p> <p>(iv) have a pack size not larger than 300mL or 300g; and</p> <p>(v) not have a therapeutic claim, including any representation about skin cancer, made for it; and</p> <p>(b) any representations in connection with the product about premature skin ageing linked to sun exposure may be made only if the product meets the performance requirements for a <b><i>broad-spectrum product</i></b> set out in clause 7.2 of <b>AS/NZS 2604:1998</b>;</p> <p>(c) any protection factor or equivalent category description stated on the product's label must be in accordance with clauses 6.2 and 6.3 of <b>AS/NZS 2604:1998</b></p>

## Attachment 4: History of the Sunscreen Standard

### First edition (1983)

The Sunscreen Standard was first published in 1983 as an Australian Standard AS 2604—1983. It described a test procedure for determining the SPF and set a limit of SPF 15+ as the maximum that could be claimed on the label.

### Second edition (1986)

The Standard was revised in 1986 and published as Australian Standard AS 2604—1986. This edition of the Standard included test procedures for determining SPF and, in addition, broad spectrum protection and water resistance. The maximum SPF claim remained at SPF 15+.

### Third edition (1993)

The Standard was again revised in 1993 and published, this time, as a joint Australian and New Zealand Standard AS/NZS 2604:1993. This (third) edition included some refinements of the category statements permitted for the different SPF ranges, but retained SPF 15+ as the maximum claim permitted.

### Fourth edition (1997)

The Standard was revised in 1997 to increase the maximum allowable SPF claim from SPF 15+ to SPF 30+ and to adjust the protection category descriptions (low, moderate, high) accordingly. There were also some other changes made to labelling requirements.

### Fifth edition (1998)

In 1998 the Standard was revised again and published on 5 October 1998 as AS/NZS 2604:1998. The changes from the 1997 edition were relatively minor.

As a result of transfer of cosmetic chemicals from the TGA to NICNAS, *Cosmetics Standard 2007* was introduced by NICNAS as a Standard for Cosmetics. The *Cosmetics Standard 2007* is a legislative instrument made under the *IC(NA) Act* and sets out the “rules” or “conditions” that apply to certain cosmetics (including cosmetic sunscreens). The old Sunscreen Standard (1998 version) is mentioned as a ‘standard’ for face and nail and skin care products categories in the *Cosmetics Standard 2007*. This is the first time that the Sunscreen Standard has been referenced within the context of NICNAS.

### Sixth edition (2012)

Over the past six years, Standards Australia and Standards New Zealand, the organisations responsible for the Sunscreen Standard, have been revising the Sunscreen Standard and bringing it into line with scientific developments and improvements in sunscreens and sunscreen standards overseas. The revised Sunscreen Standard (AS/NZS 2604:2012) was published on 30 May 2012. It includes the following changes from the old Sunscreen Standard (AS/NZS 2604:1998):

- Raising of the maximum SPF that may be claimed on the label of a sunscreen product from 30+ to 50+, limiting the permitted SPF claims to 4, 6, 8, 10, 15, 20, 25, 30, 40, 50 and 50+ (depending on the SPF test result) and removing the claim of SPF 30+ from the acceptable options. Products with SPF results between 30 and 39 may be labelled “SPF 30”, those with test results between 40 and 49 may be labelled “SPF 40”, and those with results between 50 and 60 may be labelled “SPF 50”. A claim of SPF 50+ is allowed if the mean SPF test result is 60 or higher.
- Making broad spectrum performance mandatory for all skin care cosmetic sunscreens and for face and nail sunscreen products with SPF of 30 and above.

The old Sunscreen Standard 1998 requires that all sunscreens labelled with an SPF greater than 15 to provide broad spectrum protection. However, the revised Sunscreen Standard 2012 makes a broad spectrum mandatory for all cosmetic sunscreens that are regulated by NICNAS (with SPF 4<15).

As per definition in the revised Sunscreen Standard 2012, a broad spectrum product which has been shown, using the *in vitro* test method described in appendix C of the revised Sunscreen Standard 2012, to provide protection against the sun's terrestrial UVB rays. When tested according to this method, the following performance measures shall be met: (a) *In vitro* UVA protection factor (UVAPF) shall be equal to or greater than one-third labelled SPF (b) Critical wavelength shall be equal to or greater than 370 nm.

- Changing of the criteria for categorisation of protection as 'low', 'medium' or 'moderate', 'high' or 'very high' in accordance with the wider range of SPF claims allowed.
- Adoption of the test procedure in the International Standard ISO 24443:2012 for determining broad spectrum performance. This procedure requires the degree of protection from UVA to increase with increasing SPF and is significantly more stringent than the broad spectrum test procedure in AS/NZS 2604:1998.

Some other changes to the revised Sunscreen Standard 2012, such as the following, may appear significant but, in reality, are of little or no consequence to cosmetic sunscreen products:

- Adoption of the International Standard ISO 24444:2010 *in vivo* test procedure for determining SPF. This is essentially the same as the *in vivo* test procedure in AS/NZS 2604:1998, but includes statistical criteria for acceptance of the test results. In most cases the SPF test results obtained according to AS/NZS 2604:1998 would also comply with ISO 2444:2010.
- Carrying over of the water resistance test procedure in AS/NZS 2604:1998 but adoption of the test procedure in ISO 2444:2010 for determining the SPF, and reducing the allowable claims for water resistance for sunscreens with SPF less than 30. Under the old Sunscreen Standard 1998, products with SPF 15—19 can carry water resistance claims of up to 2 hours, those with SPF 20—24 may claim up to 3 hours and products with SPF 25 or more may claim up to 4 hours. Under the revised Sunscreen Standard 2012, products with SPF of at least 15 and less than 30 can carry water resistance claims of up to 2 hours while products with SPF at least 30 and above may carry claims up to 4 hours.

It should be noted here that the water resistant aspect of the revised Sunscreen Standard 2012 does not apply to the skin care products regulated by NICNAS. However, this could apply to face and nail products as these are allowed to make a claim for water resistant.

- Specifying that 'sunblock', 'waterproof' and "sweat proof" are unacceptable terms for labelling of sunscreens.

This aspect of revised Sunscreen Standard 2012 does not apply to the products regulated by NICNAS.