

Regulation Impact Statement

Australian and New Zealand Sunscreen Standard

AS/NZS 2604:2012

**Therapeutic Goods Administration
Department of Health and Ageing
23 August 2012**

OBPR Reference 13498 Executive Summary

In Australia, primary sunscreens and some secondary sunscreens are regulated by the Therapeutic Goods Administration (TGA) as therapeutic goods and must be listed in the Australian Register of Therapeutic Goods (ARTG) in accordance with Schedule 4, Part 1, item 7 of the *Therapeutic Goods Regulations 1990*. Products to be listed must comply with the Australian and New Zealand Sunscreen Standard AS/NZS 2604:1998 *Sunscreen products—Evaluation and classification*.

Standards Australia and Standards New Zealand have recently revised and updated the Sunscreen Standard in consultation with all relevant stakeholders and the new Standard has been published as AS/NZS 2604:2012.

Under the 1998 version of the Standard sunscreens can be labelled with a sun protection factor (SPF) rating of no more than SPF 30+, whereas the new Standard allows products to be labelled with a rating up to SPF 50+. The new Standard also sets more stringent requirements for the broad spectrum performance. The intention of these changes is to harmonise the AS/NZS Standard with international standards and to encourage the development and marketing of sunscreens that deliver much greater protection from the Sun's UV radiation with a view to reducing the incidence of skin cancer in Australia and New Zealand.

If adopted, the new Standard would result in substantial one-off costs to industry (estimated at \$45,000 - \$175,000 per product) incurred in developing, listing and launching products delivering significantly better protection from harmful UV radiation than those currently available in Australia. Consumers would face 15% to 30% increases in prices, but the increased health benefits of using the new generation sunscreens would, in the longer term, greatly outweigh those cost increases.

There would be no initial costs to Government, but in the longer term as skin cancer rates declined as a result of Australians using better sunscreen, there would be reduced costs to Government in providing health services to skin cancer patients. The current cost is about \$300 million per year. It is not possible to quantify with any precision the expected difference that adoption of the new Standard could make to skin cancer rates, but a modest 5% to 10% reduction would mean a saving of \$15 million to \$30 million per year to the Australian health systems. The TGA, the sunscreen industry and other relevant stakeholders are well aware of the financial implications of applying the new Standard, have been involved throughout the Standard revision process and fully support adoption of the new Standard for sunscreens to be listed in the ARTG and marketed in Australia.

The TGA therefore recommends that Schedule 4, Part 1, item 7(a), Schedule 5, item 8, paragraph (g) and Schedule 7, item 14 of the *Therapeutic Goods Regulations 1990* be amended appropriately to recognise AS/NZS 2604:2012 as the legal requirement for sunscreens entering the ARTG as from the date the amendments come into force but also to allow sunscreens listed in the ARTG prior to that date to remain listed in the ARTG.

Allowing sunscreens that comply with AS/NZS 2604:1998 (but not with AS/NZS 2604:2012) and were listed in the ARTG prior to the amendments coming into force to remain listed and available in the Australian market would avoid major disruption of the supply of sunscreens in Australia or write-off of existing stock and it would allow manufacturers and sponsors time to bring their product ranges into line with the new Standard.

If the Regulations are amended to recognise AS/NZS 2604:2012 as the Sunscreen Standard for Australia, the industry will be advised and the *Australian Regulatory Guidelines for Sunscreens* detailing the requirements for sunscreens complying with the new Standard will be finalised and published by the TGA to ensure that sponsors and manufacturers are fully informed of the legislative and other requirements for these products.

1. Problem

1.1 The Importance of Sunscreens

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. Overexposure to UV radiation from the sun is responsible for almost all skin cancers. The actual damage that leads to skin cancer may occur many years before the cancer actually appears.

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. In 2008 there were a total of 1850 deaths from skin cancer in Australia (1430 from melanoma and 420 from non-melanoma skin cancer). The diagnosis and treatment of skin cancer costs the Australian health system around \$300 million per year.¹

The use of sunscreens is one of five measures that dermatologists, cancer specialists, cancer councils and societies, and public health authorities recommend should be taken in combination to reduce the risk of sun damage and skin cancer, namely:

1. sunscreen (preferably 'broad spectrum', water resistant and with a high or very high sun protection factor [SPF]) applied liberally before exposure of the skin to sunlight and reapplied liberally every two hours (or more often if sweating or swimming);
2. sun-protective clothing;
3. a hat that protects the face, head, neck and ears;
4. sunglasses that provide protection from ultraviolet radiation; and
5. keeping to the shade as much as possible and avoiding excessive exposure of the skin to direct or reflected radiation from the sun.

Many Australians use sunscreen every day of their lives, sometimes over large areas of their body surface. Unfortunately, many do not apply sunscreens as liberally as recommended and therefore do not receive the degree of protection that they offer when used correctly. Therefore, it is important that sunscreens used in Australia are safe, effective and of acceptable quality, and that consumers have access to sunscreens that provide maximal protection from the sun's UV radiation to compensate, if possible, for deficiencies in the amount applied to the skin.

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

¹ <http://www.sunsmart.com.au>

considered to be mainly responsible for the longer term damage resulting in melanomas and other skin cancers. If not removed in time melanomas and other skin cancers can lead to serious disfigurement or death.

Sunscreens are generally tested for two properties:

1. their “sun protection factor” (SPF) which measures the degree of protection against UVB radiation, and
2. their “broad spectrum performance” which is a measure of the degree of protection from UVA radiation.

Many sunscreens are designed to be used while swimming or surfing and are tested for their “water resistance” to determine how well they adhere to the skin in water and how often they need to be reapplied.

The Australian and New Zealand Sunscreen Standard AS/NZS 2604:1998 *Sunscreen products – Evaluation and classification* currently in force in Australia and New Zealand details the test procedures and criteria for determining the SPF, broad spectrum performance and water resistance of sunscreens. The SPF and water resistance are tested on human skin, whereas the broad spectrum performance is measured using a laboratory instrument designed for the purpose.

The SPF is measured by irradiating with intense artificial UV light small areas of unprotected skin and skin to which a sunscreen has been applied at a rate of 2 milligrams per square centimetre and determining the ratio of the times required to produce reddening of the skin. For example, if such reddening it took 10 seconds for unprotected skin and 350 seconds for protected skin, the SPF result would be calculated in this case by dividing 350 seconds by 10 seconds, yielding a result of 35. The test is carried out on 10 individual volunteers and the individual SPF results are averaged.

In the water resistance test, the sunscreen is applied to the volunteers’ skin and they immerse the area concerned in a pool of water for a period of time. Then after being dried in air, the skin is irradiated and the SPF is determined as in the “static” method above. The water resistance rating (in minutes or hours) that can be declared on the product label is the total time the test areas of skin were immersed.

In the broad spectrum performance test, UVA radiation is passed through the sunscreen to determine how much is transmitted at each wavelength across the UVA range (320-400 nanometres). The sunscreen is either spread on a quartz plate at a rate of 2 milligrams per square centimetre or is dissolved in a solvent in a special vessel so that the amount of sunscreen is equivalent to 2 milligrams per square centimetre across the area of the light beam. To pass the test, no more than 10% of the radiation may pass through the sunscreen layer or solution at any wavelength across the UVA range. That is equivalent to saying that the sunscreen must block at least 90% of the radiation at each UVA wavelength.

1.2 Regulation of Sunscreens in Australia

In Europe and in New Zealand sunscreens are classified and regulated as cosmetics whereas in Canada and the USA they are regulated as “drug products”.

In Australia, sunscreens fall into two categories: “therapeutic sunscreens” and “cosmetic 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 Therapeutic Goods Administration (TGA) and must be listed in the Australian Register of Therapeutic Goods (ARTG).
- Secondary sunscreens (products that contain suncreening agents but whose primary purpose is something other than suncreening) 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 *Cosmetic Standard 2007* and regulated by the National Industrial Chemicals Notification and Assessment Scheme (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 any SPF, and
- lip-sticks and lip balms with sunscreen with any SPF.

Cosmetic sunscreens must comply with the relevant sections of the 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 detailed in the *NICNAS Cosmetic Guidelines* published by NICNAS.

Primary sunscreens and those secondary sunscreens that are not “cosmetics” are therapeutic goods and must be listed in the ARTG. To qualify for listing they must have been tested and labelled in accordance with the AS/NZS Sunscreen Standard. Their labelling must also comply with *Therapeutic Goods Order No. 69 – General requirements for labels for medicines* (TGO 69).

Furthermore, they must be manufactured and packed by manufacturers that comply with the TGA’s Code of Good Manufacturing Practice. These regulatory requirements are designed to ensure that these products are of consistently high quality and effectiveness.

These requirements and differences are summarised in the table below.

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

1.3 References to the Sunscreen Standard in the Therapeutic Goods Regulations 1990

The Sunscreen Standard AS/NZS 2604:1998 is referred to three times in the Therapeutic Goods Regulations, namely, in Schedules 4, 5 and 7. See Appendix 1 for the full texts of the relevant items concerned.

According to **Schedule 4, Part 1, item 7** of the Regulations, a sunscreen product is eligible for listing (rather than registration) in the ARTG if it is not indicated for the treatment of a disease, condition, ailment or defect *and* it has been tested for SPF according to AS/NZS 2604:1999 *and* it has an SPF not less than 4 *and* its labelling (including performance statements) complies with that Standard.

A sunscreen with an SPF less than 4 is eligible for listing in the ARTG if it is not indicated for the treatment of a disease, condition, ailment or defect *and* it has been tested for SPF according to AS/NZS 2604:1998 *and* its labelling (including performance statements) complies with that Standard *and* it contains an ingredient that is of human origin or of animal origin if it is or is derived from certain specified animal materials. It should be noted that there are no sunscreens containing any of those ingredients of human or animal origin listed or registered in the ARTG.

There is only one sunscreen currently registered rather than listed in the ARTG, and that is because it is not only a primary sunscreen, but it is also indicated for the prevention of UV induced immune-suppression.

According to **Schedule 5, item 8, paragraph (g)** of the Regulations, a sunscreen product is not required to be included in the ARTG if its SPF has been tested according to AS/NZS 2604:1998 and found to be less than 4 *and* its labelling (including performance statements) complies with that Standard *and* it does not contain an ingredient that is of human origin or of animal origin if it is or is derived from one of the same animal materials specified in Schedule 4, Part 1, item 7.

It should be noted, however, that neither the 1998 nor the 2012 version of the Sunscreen Standard allows SPF claims of less than 4.

According to **Schedule 7, item 14** of the Regulations, a sunscreen product is exempt from the requirement to be manufactured in accordance with the Code of Good Manufacturing Practice (unless supplied as a pharmaceutical benefit) if its SPF has been tested according to AS/NZS 2604:1998 and found to be less than 4 *and* the product labelling indicates that the SPF is less than 4.

1.4 The Need for a New Standard

The Sunscreen Standard was first published in 1983 and was revised in 1986, 1993, 1997 and 1998.. The original *Therapeutic Goods Regulations 1990* referred to the 1996 edition of the Standard, which set SPF 15+ as the maximum claim allowed on sunscreen label. The 1997 edition of the Standard raised the maximum SPF claim to SPF 30+.

When the Standard was revised in 1993, 1997 and 1998 the regulations were amended to recognise the latest edition. For further details of the history of the Standard and its recognition in the Regulations, see Appendix 2.

The Sunscreen Standard (AS/NZS 2604:1998) currently referred to in the Regulations sets SPF 30+ as the maximum that may be claimed on the label. To qualify for a “30+” rating a sunscreen must have yielded a SPF test result of 31 or higher, and must also have passed the broad spectrum performance test.

As at 1 June 2012 there were 911 sunscreen products on the ARTG. Approximately 860 (95%) were rated SPF 30+. Their actual SPF test results as reported to the TGA were mostly in the mid 30’s, but a few were in the 40’s and 50’s. However, the present mandatory labelling of all these products with “SPF 30+” does not allow consumers to identify and select them on the basis of their actual SPFs.

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+ and which provide more protection from UVA radiation (as determined by the “broad spectrum performance” test).

The current Sunscreen Standard applying in Australia has become out of date and now acts as an obstacle to introduction into the Australian market of sunscreens that can deliver superior protection from both UVA and UVB damage to the skin and reduce further the incidence of skin cancer in this country.

Ironically, while AS/NZS 2604 is a joint Australian and New Zealand Standard, sunscreens marketed in New Zealand do not necessarily have to comply with that Standard, and consequently sunscreens labelled with SPF values much higher than SPF 30+ are already available for sale in New Zealand.

Maintaining an SPF limit of 30+ has also created a potential trade barrier by preventing the export of higher-SPF products to Australia, and has limited the ability of Australian manufacturers to market higher-SPF products in both Australia and overseas. Sunscreens with SPF values much higher than SPF 31 are more expensive to produce and would be uncompetitive in the market unless their much higher SPF values could be indicated on the label and serve to justify their higher prices to consumers.

Consequently, requiring adherence to AS/NZS 2604:1998 has meant that Australia has lagged behind the rest of the world in terms of access by its public to the most effective and beneficial sunscreens. This has been recognised by the sunscreen industry in Australia and has been a stimulus for updating of the Standard.

1.5 The New Standard

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

The resulting new Standard, AS/NZS 2604:2012, was published on 30 May 2012. The 1998 version of the Standard is now no longer available for purchase, but the Regulations still require compliance with the 1998 Standard.

The sunscreen industry and other relevant stakeholders are very keen to see the Therapeutic Goods Regulations amended as soon as possible to recognise the new Standard so that sunscreens complying with the new Standard and with SPF claims higher than SPF 30+ can be listed in the ARTG and allowed onto the Australian market.

The new Standard includes the following significant changes from the current Standard (AS/NZS 2604:1998) designed to improve greatly the UV protective performance of sunscreens:

- 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.

Note that a typical SPF 50+ sunscreen complying with the new Standard would provide about twice the protection against UVB radiation provided by a typical SPF 30+ sunscreen complying with the current Standard.

- 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, as tabulated below.

Protection Category	Current Standard	New 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+

Note that, under the current Standard, a sunscreen labelled SPF15 to SPF 29 may be labelled “ High Protection” whereas, under the new Standard, a product would need to be labelled SPF30 to SPF50 to be labelled with “High Protection”.

Under the current Standard a sunscreen labelled SPF30+ (usually supported with a test result in the range 31-39) may be labelled “Very High Protection” whereas, under the new Standard, a product would need to be labelled SPF50+ (with a test result of 60 or higher) to be labelled “Very High Protection”.

The current criteria are out of date and out of line with the new generation sunscreens already available overseas. The new criteria are more realistic and better reflect the protective capacities of the different SPFs.

The changes might prove somewhat confusing for some consumers for a while but, as current products with SPFs in the range 15 to 30+ disappeared from the market as anticipated once SPF 40, 50 and 50+ products became available and well-known, that confusion would resolve itself.

- 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.

Note that a typical SPF 50+ sunscreen complying with the new Standard would provide 10—20 times the protection against UVA radiation provided by a typical SPF 30+ sunscreen complying with the current Standard.

- Making broad spectrum performance mandatory for all primary sunscreens and secondary sunscreens classified as ‘therapeutic sunscreens’ and regulated by the TGA.

Note that the current Standard requires all sunscreens labelled with an SPF greater than 15 to provide broad spectrum protection.

There are only 5 primary sunscreens (less than 1% of the total) in the ARTG with SPF 15 or less and not required by the current Standard to be “broad spectrum”. However, only one of those five products is not actually “broad spectrum” and it is not currently marketed.

The only secondary sunscreens listed with SPF less than 15 and not required to be “broad spectrum” are 3 sun-tanning products with SPF 6 or 8. However, these products are cosmetics and are not required to be in the ARTG. They are very old products and it is not known if they are still marketed. In any case, cosmetic

sunscreens are regulated by the ACCC and NICNAS and are not affected by the proposed changes to the Therapeutic Goods Regulations.

While current products provide broad spectrum protection as defined in the current Standard, that protection is not as effective as that required by the new Standard. The new Standard is intended to improve greatly the protection provided by sunscreens in the Australian and New Zealand markets.

Some changes to the Standard, such as the following, may appear significant but, in reality, are of little or no consequence.

- 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 additional statistical criteria for acceptance of the test results designed to improve their accuracy and reproducibility. In most cases the SPF test results obtained according to AS/NZS 2604:1998 would also comply with ISO 24444:2010.

- Carrying over of the water resistance test procedure in AS/NZS 2604:1998 but adoption of the test procedure in ISO 24444:2010 for determining the SPF, and reducing the allowable claims for water resistance for sunscreens with SPF less than 30. Under the current Standard, 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 new Standard, 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.

As far as the TGA can determine, all of the water resistant sunscreens currently listed in the ARTG have SPF30+ and, under the current Standard, can carry water resistance claims of up to 4 hours. Under the new Standard, water resistance up to 4 hours can be claimed for products with SPF 30, 40, 50 or 50+.

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

Note that these terms are already recognised to be misleading and therefore are not currently acceptable claims under Section 4 (2) of the *Therapeutic Goods Advertising Code 2007*. The new Standard does not change, but simply incorporates and makes quite clear the current requirements.

While the SPF test (and water resistance) procedures and requirements in the current and new Standards are essentially the same, most currently available SPF 30+ sunscreens could not simply be relabelled with SPF 30 or SPF 40 (depending on the SPF tests results).

According to the two Australian testing laboratories for sunscreens (Dermatest and APTF) about 80% of the available SPF 30+ sunscreens (i.e. 700—750 products) listed in the ARTG would not comply with the new broad spectrum test in ISO 24443:2012 and therefore would not comply with AS/NZS 2604:2012.

There is therefore a need not only for a Sunscreen Standard that allows for sunscreens that provide better protection than those that the current Standard allows, but also there is a need for the availability of those better products in the Australian market and the phasing out of the less effective products to be actively encouraged.

According to data published by the Australian Institute of Health and Welfare,² the overall rate of skin cancer (both melanoma and non-melanoma) per 100,000 in the Australian population has more than doubled over the past 30 years. However, over the past 15 years, while the rate has continued to increase for those aged over 50 years, the rate has levelled off for those aged 25-49 years and has been decreasing by about 3% per year for those aged under 25 years.

The TGA believes that the downward trend in the rates for younger Australians is the result of two factors: firstly, their greater use of sunscreens as a result of increased promotion and public awareness of the importance and benefits of sunscreens, and secondly, the availability of more protective sunscreens since 1997 when the Sunscreen Standard was amended to allow and encourage products with significantly higher Sun Protection Factors (SPF) (30+ as opposed to 15+) and better protection across the harmful UV wavelength range than previously required. The TGA believes that availability of sunscreens providing even higher protection would result in even greater reduction in skin cancer rates in the years to come.

2. Objectives

The *primary* objective of regulation of primary and many secondary sunscreens in Australia as therapeutic goods by the TGA is to ensure their quality, safety and efficacy with a view to protecting consumers from the sun's harmful UV radiation and reducing the incidence and tragic outcomes of skin cancer. The requirement that these products comply with the Sunscreen Standard is a vital part of the assurance of quality, safety and efficacy.

A *secondary* objective of regulation of sunscreens is minimising costs for business where it does not compromise the primary objective above in order to ensure the commercial viability of the Australian sunscreen industry and the continued availability of sunscreens to Australian consumers

3. Options

Schedules 4, 5 and 7 of the Regulations currently refer to the Standard AS/NZS 2604:1998 and require that sunscreen products listed in the ARTG must have their SPF tested according to that Standard and that their labelling comply with that Standard. Sunscreens destined for the Australian market (but not the overseas market) must also comply with the labelling requirements for medicines as set out in the Labelling Order (TGO 69).

As noted above, the test procedures for SPF in the current and new Standards are essentially the same and would deliver the same mean test result. However, a sunscreen with a very high SPF could not be labelled with an SPF higher than SPF 30+ unless the new Standard is adopted in the Therapeutic Goods Regulations.

Schedule 4, Part 1, item 7 (b) requires the labelling of listed sunscreens to comply with Standard. The labelling includes the broad spectrum performance claim. The broad spectrum test in the new Standard is more stringent than that in the current Standard and a product that was tested according to the new (2012) Standard would comply with the broad

²See <http://www.aihw.gov.au/acim-books/>

spectrum requirements of the current (1998) Standard. However, many currently listed sunscreens would not comply with the new broad spectrum test.

There are two possible options regarding adoption or otherwise of the new Sunscreen Standard:

Option 1: Maintain the status quo and do not amend the Regulations to adopt the new Standard

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

- Sunscreen labelling in Australia would be out of line with international practice and this would also act as a disincentive to companies wishing to develop and market in Australia sunscreens that deliver much better protection from UV radiation than those currently available.
- The additional protection against UV radiation delivered by very high SPF broad spectrum sunscreens would not be available to Australian consumers and in the long term this could mean that some consumers could eventually develop (and possibly die from) skin cancers that could otherwise be prevented.

Option 2: Adopt the new Standard for new sunscreen products but allow currently-listed products to remain in the ARTG

Adopting this option would have the following consequences:

- New sunscreen products with SPF claims up to 50+ could be listed in the ARTG as soon as the new Standard was adopted and could lawfully enter the market.
- There would be no ambiguity about the status of products currently listed in the ARTG. Sunscreens complying in all respects with the current Standard and listed on the ARTG prior to adoption of the new Standard could remain listed in the ARTG and on the Australian market at manufacturers' and sponsors' discretion or until market forces made them uncompetitive due to the availability of products with higher SPF claims. This would avoid any major disruption to availability of sunscreens and avoid write-offs of stock.
- There are only 28 primary sunscreens with SPFs in the range 4 to 30 and 16 moisturisers with sunscreen with SPFs in the range 15+ to 25 in the ARTG. The overwhelming majority of the sunscreens currently listed are labelled SPF30+. Although the new Standard allows SPF claims in the range 4 to 30, it is unlikely that many, if any, such products would be listed if the new Standard is adopted. New products are much more likely to have SPF40, SPF 50 or SPF50+ and consumers would generally be able to distinguish the older generation products by their SPFs of 30+ or less from the new generation products with their SPFs of 40, 50 or 50+. Sunscreens currently listed in the ARTG could be retested where appropriate according to the new Standard and, depending on the results, could either be relabelled and re-listed in the ARTG, or be reformulated, retested, labelled and re-listed in the ARTG.

When the SPF limit was raised from SPF 15+ to SPF 30+ in 1997 the number of SPF 15+ sunscreens listed in the ARTG quickly declined and these products were replaced by products with SPF30+. Only about 4% of the SPF 15+ products that were in the ARTG in 1997 remain listed. It is not known how many of these are actually marketed.

There was no legislated requirement for SPF15+ products to be cancelled when AS/NZS 2604:1997 was adopted. Instead, market forces and other commercial considerations led manufacturers and sponsors to discontinue marketing of most of their SPF15+ products and to replace them with SPF30+ products. It is reasonable to expect that a similar market-driven phasing out of SPF30+ products in favour of products with higher SPFs would occur within a few years of AS/NZS 2604:2012 being recognised in the Regulations.

It should be noted that sunscreens with SPF 30+ are not unsafe and they still provide good protection from UV radiation, even if they are not as protective as products with higher SPF ratings.

4. Impact Analysis

As at 1 June 2012 there were 911 primary and secondary sunscreen products listed in the ARTG. However, the number of actual formulations was much less than 911 because sunscreen manufacturers commonly produce formulations that are marketed by several different sponsors under a variety of brand names.

According to recent data provided by the industry, annual sales of primary sunscreens in Australia amount to 6.6 million units with a retail value of \$72 million. About 4.4 million units valued at \$49 million are sold through grocery outlets and about 2.2 million units valued at \$29 million are sold through pharmacies.

The anticipated impacts of not adopting or adopting the new Sunscreen Standard on the different stakeholders would be as summarised below.

4.1 Impacts of Option 1 (Maintenance of the status quo)

a. Impact on Australian manufacturers

About 85% of the sunscreens currently listed in the ARTG are manufactured in Australia by Australian owned companies. These Australian manufacturers would be able to continue developing, producing and marketing in Australia sunscreens that comply with the 1998 Standard.

They would be able to develop and manufacture sunscreens with SPFs greater than SPF 30+, but only for export to overseas markets where the higher SPF claims are permitted. Some manufacturers already do so, but they do not receive the additional financial benefits of economy of scale that would result if the Australian market could also be included.

b. Impact on foreign manufacturers

About 15% of the sunscreens currently listed in the ARTG are manufactured overseas. Their foreign manufacturers would be able to continue producing and exporting to Australia sunscreens that comply with the 1998 Standard but not sunscreens with SPFs greater than SPF 30+ permitted elsewhere in the world. The Australian market might become increasingly less attractive to them.

c. Impact on Australian sponsors

All sunscreens listed in the ARTG have an Australian sponsor and there are approximately 150 sponsors involved. Some of these sponsors are also manufacturers. Most source their products from contract manufacturers in Australia or overseas. They would be able to continue marketing their current products and other products that comply with the current Standard, but would not be able to market products with the higher SPF claims allowed under the new Standard.

d. Impact on Australian consumers

Consumers would be able to continue using products that comply with the current Standard, but would not be able to purchase products with the higher SPF claims allowed under the new Standard. They would effectively be denied access to products that provide much better protection from the sun's UV radiation and the opportunity to further reduce their risks of developing skin cancer.

e. Impact on the Australian Government

The cost of skin cancer treatment to the Australian health system is currently about \$300 million per year. A reduction in UV damage and skin cancer rates through the use of more protective sunscreens by Australians could be expected to reduce that financial burden in the longer term, but not adopting the new Standard would produce no such reduction.

f. Overall impact of Option 1

Maintenance of the status quo would save industry and consumers money in the short term, but in the longer term it would deny Australian consumers access to the benefits of very high SPF sunscreens with superior protective properties that could reduce the risk of developing skin cancer and reduce the associated costs to the health systems. Furthermore, lives could be lost that otherwise could be saved.

4.2 Impacts of Option 2 (Adoption of the new Standard)

Option 2 allows companies to continue to produce and market their currently listed sunscreen products and to produce and market products complying with the new Standard. They would not be compelled by the Regulation changes per se to discontinue marketing their current products. However, market forces would inevitably make such products less marketable once products with much higher SPFs became available.

The Standard was revised in 1997 to increase the maximum allowable SPF claim from SPF 15+ to SPF 30+ and the Regulations were amended soon afterwards to adopt the revised Standard (AS/NZS 2604:1997). At that time there were 440 SPF 15+ sunscreens listed in the ARTG. Within 3 years 69% of these had been cancelled from the ARTG, within 6 years 83% had been cancelled, within 10 years 90% had been cancelled, and within 15 years 96% had been cancelled. There are currently only 16 SPF 15+ sunscreens remaining listed in the ARTG.

The overwhelming majority of sunscreens currently listed in the ARTG are rated as SPF 30+ and comply with the current broad spectrum test. Based on what happened when the SPF limit was raised from SPF 15+ to SPF 30+, it is reasonable to assume that the marketability of SPF 30+ products would decline within a few years once much higher SPF products became available. Manufacturers and sponsors would be forced by consumer demand to replace

their product ranges with the higher SPF products allowed under the new Standard. This replacement process might be by reformulation of existing products or by development of completely new products.

According to information provided by the sunscreen industry through Accord and ASMI and by the Australian testing laboratories (Dermatest and APTF) the likely costs for the various elements involved in developing and launching new sunscreens or bringing existing sunscreen products into line with the new Sunscreen Standard are as tabulated below.

Developmental Costs	Cost (excl. GST)
Development and validation of a revised or new formulation (including stability testing)	\$40,000 - \$160,000
Testing for SPF: Non-water-resistant product	\$2,000 - \$3,000
Water-resistant product	\$4,000 - \$,7000
Testing for "broad spectrum" performance	\$400 -600
Labelling changes or development	\$3,000 - \$6,000
Total cost:	\$45,000 - \$175,000

The costs of development, testing and labelling are essentially the same regardless of which standard (1998 or 2012 version) the product must comply with.

Achieving the higher SPFs and more stringent broad spectrum performance of the new generation sunscreens would mean increased costs for manufacturers and sponsors. However, the sunscreen market is dynamic and there is already a continual flow of new sunscreens into the ARTG and onto the Australian market and consequent discontinuation of products that sponsors no longer wish to market.

a. Impact on Australian manufacturers

About 85% of the sunscreens currently listed in the ARTG are manufactured in Australia by Australian owned companies. Adoption of the new Standard would allow these companies to develop and market much more effective sunscreens both in Australia and overseas and to reap the benefits of the economies of scale that would result. However, for each reformulated or new product they would face the substantial development costs tabulated above.

Companies could continue producing their current sunscreen products unchanged and in that case there would be no initial financial or regulatory impact from adoption of the new Standard, but before long those products would inevitably become less marketable in the face of competition from products with much higher SPFs became available and the companies concerned would be forced to invest in reformulated or completely new products.

b. Impact on foreign manufacturers

About 15% of the sunscreens currently listed in the ARTG are manufactured overseas. Their foreign manufacturers are likely to have already developed very high SPF products for markets outside Australia and they would then be able to export them to Australia without having to face the financial burdens 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.

These foreign companies could continue producing their current Australian specific sunscreen products unchanged and in that case there would be no initial financial or regulatory impact from adoption of the new Standard, but before long those products would inevitably become less marketable in the face of competition from products with much higher SPFs became available and the companies concerned would be forced, like their Australian counterparts, to invest in reformulated or completely new products.

c. Impact on Australian sponsors

All sunscreens listed in the ARTG have an Australian sponsor and there are approximately 150 sponsors involved. Some of these sponsors are also manufacturers. Most source their products from contract manufacturers in Australia or overseas. They would be able to continue marketing their current products and other products that comply with the current Standard, but would also be able to market products with the higher SPF claims allowed under the new Standard and to compete for a share of the Australian market.

Sponsors carry the regulatory costs of listing and maintaining their products in the ARTG. These relevant TGA fees are tabulated below and are very modest compared to the costs involved in producing reformulated or new sunscreen products.

Regulatory Fees	Cost (incl. GST)
Listing in the ARTG (1/7/2012 fees, incl. GST):	
Application fee	\$720
Processing fee for variation to existing listing	\$360
Annual charge for maintaining listing in the ARTG	\$910

d. Impact on Australian consumers

If the new Standard was adopted and products complying with the 1998 Standard were allowed to remain listed in the ARTG Australian consumers would have a greater choice of sunscreens. They could continue purchasing SPF 30+ products that comply with the current Standard, but would also be able to purchase products with the higher SPF claims allowed under the new Standard and so have the opportunity to further reduce their risks of developing skin cancer.

The industry estimates that the price to the consumer of a typical SFP50+ sunscreen would be 15% to 30% higher than a typical SPF 30+ product. However, while consumers would face increased prices for very high SPF sunscreens, the products concerned would provide a much greater percentage increase in protection from the risks of skin damage and cancer than the currently available products can deliver.

There is a long lead time from UV damage to the appearance of melanoma or non-melanoma skin cancer, and so it would take some years before the benefits would be recognised. It is not possible to quantify the expected difference adoption of the new Standard would make to skin cancer rates, but even if it was only a 5% to 10% reduction in skin cancer rates, that would mean 100 to 200 lives saved per year.

e. Impact on the Australian Government

There would be no cost to the Government involved in listing and regulating new generation sunscreens. The TGA is fully funded by fees paid by the industry. The one-off costs involved in adjusting the software of TGA's Electronic Lodgement Facility (ELF) to accommodate products with the higher SPF's allowed under the new Standard are negligible.

It is not possible to quantify with any precision the expected difference that adoption of the new Standard could make to skin cancer rates, but a modest 5% to 10% reduction would mean a saving of \$15 million to \$30 million per year to the Australian health systems.

f. Overall impact of Option 2

As outlined above, adoption of the new Standard and the ensuing changes to the sunscreens available in Australia would result in some substantial one-off costs for industry and ongoing increased prices faced by consumers. On the other hand, the benefits to the public would be the availability of clearly identifiable sunscreens with superior protective properties that could reduce the risk of developing skin cancer and reduce the associated costs to the health systems from of treatment of preventable skin cancers. Furthermore, lives could be saved that otherwise would be lost.

5. Consultation

The Australian and New Zealand Standards organisations have carried out extensive stakeholder and public consultation regarding the new Sunscreen Standard. The draft document was developed over a lengthy period of time by the Joint Sunscreen Standard Committee (Committee CS-042) of Standards Australia and Standards New Zealand.

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.

Committee CS-042 was composed of representatives from the following large number of relevant Australian and New Zealand Government, industry, consumer and professional organisations, namely:

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

Accord Australasia is the industry “peak body” for the Australian cosmetic industry while ASMI is the peak body for the non-prescription medicines industry. As at 1 June 2012 there were 911 sunscreen products listed in the ARTG. Of these products: 86% were manufactured in Australia; 71% were manufactured by companies that are members of Accord Australasia or ASMI; 50% were sponsored by companies that are members of Accord or ASMI; and 83% were manufactured and/or sponsored by that are members of Accord or ASMI. Accord and ASMI together represent the interests of the companies responsible for the overwhelming majority of the sunscreens listed in the ARTG.

Thus, throughout the development of the new Standard, the industry was well represented and had significant input into the formulation of the draft document.

Through its delegates on the Committee, the TGA also had significant input into the revision process and ensured that the outcomes were in line with current legislative requirements for sunscreens and with Government health policies.

The draft document was published for stakeholder and public consultation on the Standards Australia website in May-July 2011. Standards Australia issued press releases to ensure that interested parties were aware of the consultation and had the opportunity to contribute.

The Consultation attracted a large number of submissions from organisations and individuals with 307 individual comments and suggestions for improvements to the document. The suggestions were mostly of an editorial nature or suggestions for clarification or refinement of some of the technical details. No opposition to the proposed major changes to the Standard (raising the SPF limit to SPF 50+, harmonising test procedures with the relevant International Standards, and requiring broad spectrum performance for more categories of sunscreens) were expressed in the submissions.

Committee CS-042 met in September 2011 to consider the submissions and, where appropriate, revise the draft document in light of these submissions. All of the suggestions for improvement were given careful consideration and most were adopted.

One submission (from a concerned member of the public) referred to nanoparticles in sunscreens and recommended changes to Government Regulations and TGA requirements to ensure that the safety of nanoparticles in sunscreens is assessed by the TGA and their presence is declared on the label. The comments were a matter for the TGA and outside the scope of the Standard. Consequently, the Committee did not recommend making any changes to the Standard in response. It should be noted that the TGA has reviewed the

matter of nanoparticles in sunscreens (and continues to maintain a watching brief on the subject) and has published its findings and conclusions on its website.³

The revised draft Standard was finally submitted to the Committee for a ballot in April 2012. Committee members voted on behalf of their organisations and the result was an overwhelming vote in favour of publishing the document as AS/NZS 2604:2012 to supersede AS/NZS 2604:1998. All major stakeholders supported publication the new Standard.

The new Standard was published as AS/NZS 2604:2012 on 30 May 2012. However, it has no legal force in Australia until adopted in the *Therapeutic Goods Regulations 1990* and, until that happens, sunscreens to be listed or registered in the ARTG must comply with the previous Standard AS/NZS 2604:1998

6. Conclusion

Australia has lagged behind other comparable countries in its regulation of sunscreens and the availability in the market of products that deliver very high protection from the sun's UV radiation. Standards Australia and Standards New Zealand have addressed this issue by revising the Sunscreen Standard in full consultation with all of the relevant stakeholders and the Australian public. The TGA has played an active role in that revision process, and has ensured that any changes are in harmony with current legislative requirements for sunscreens and with Government health policies.

The TGA is satisfied with the final Standard AS/NZS 2604:2012 and supports its adoption as a replacement for the current, out-of-date Standard AS/NZS 2604:1998. The TGA is also satisfied that the longer-term health benefits to Australians resulting from adoption of AS/NZS 2604:2012 and amendment of the *Therapeutic Goods Regulations 1990* accordingly would outweigh the initial costs to those affected by the need to change or replace currently marketed sunscreens and the cost to consumers resulting from increased retail prices of sunscreens.

The TGA therefore recommends that Schedule 4, Part 1, item 7(a), Schedule 5, item 8, paragraph (g) and Schedule 7, item 14 of the *Therapeutic Goods Regulations 1990* be amended appropriately to recognise AS/NZS 2604:2012 as the legal requirement for sunscreens entering the ARTG as from the date the amendments come into force but also to allow sunscreens listed in the ARTG prior to that date to remain listed in the ARTG.

Allowing sunscreens that comply with AS/NZS 2604:1998 (but not with AS/NZS 2604:2012) and were listed in the ARTG prior to the amendments coming into force to remain listed and available in the Australian market would avoid major disruption of the supply of sunscreens in Australia or write-off of existing stock and it would allow manufacturers and sponsors time to bring their product ranges into line with the new Standard.

³ See "A review of the scientific literature on the safety of nanoparticulate titanium dioxide or zinc oxide in sunscreens", <http://www.tga.gov.au/pdf/review-sunscreens-060220.pdf>

7. Implementation

If and when the Regulations are amended to recognise AS/NZS 2604:2012 as the Sunscreen Standard for Australia, the TGA will make the necessary adjustments to its Electronic Lodgement Facility to allow sunscreens with SPFs higher than 30+ to be listed.

While the Sunscreen Standard Committee was carrying out its revision of the Standard, the TGA was carrying out a revision of its Sunscreen Guidelines currently available as Chapter 10: Sunscreens in the *Australian regulatory guidelines for OTC medicines* (ARGOM). The TGA was assisted in this work by a working group composed of representatives from Accord, ASMI and NICNAS.

The draft Guidelines were published for stakeholder and public comment in May-June 2010.⁴ Submissions were received from 11 organisations and individuals (including Accord Australasia and ASMI). Almost all of the recommendations for improvement were adopted. However, the TGA made the decision to delay finalisation and publication until the new Standard was available and was formally adopted into the *Therapeutic Goods Regulations 1990* so that its requirements could be reflected in the final text.

It is intended that the sunscreen guidelines will be published as a stand-alone document entitled *Australian Regulatory Guidelines for Sunscreens* once the Regulations are amended to recognise the new Standard. The submissions received during the consultation on the *Guidelines* and the TGA's responses to those submissions will also be published.

Listed medicines are not evaluated by the TGA prior to inclusion in the ARTG but applications for listing are accepted on the basis of declarations by the sponsors concerned that they have complied with all of the applicable requirements for the products concerned. However, the TGA has the legislative power to carry out audits by requesting sponsors to submit documentary evidence of the compliance that they have declared during the listing process. The TGA intends to carry out appropriate audits to ensure that sponsors understand and comply with all of the requirements for these products. If problems are identified through these audits the sponsors concerned will be advised accordingly and required to rectify the situation.

⁴ See <http://www.tga.gov.au/archive/consult-otc-argom-sunscreens-100505.htm>

Appendix 1: References to the Sunscreen Standard in the Therapeutic Goods Regulations 1990

The Sunscreen Standard AS/NZS 2604:1998 is referred to in Schedules 4, 5 and 7 of the Therapeutic Goods Regulations, as follows:

According to **Schedule 4, Part 1, item 7** of the Regulations, sunscreen products are eligible for listing in the ARTG where they meet the following criteria:

'Sunscreen preparations for dermal application (other than preparations for the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code), if:

- (a) the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:1998, as in force from time to time; and*
- (b) the performance statements and markings on the label comply with that Standard; and*
- (c) the sun protection factor stated on the label is:*
 - (i) 4 or greater; or*
 - (ii) less than 4 and the preparations include an ingredient of human origin, or animal origin if the ingredient consists of, or is derived from, any of the following parts of cattle, sheep, goats or mule deer:*
 - (A) adrenal, (B) brain, (C) cerebro-spinal fluid, (D) dura mater, (E) eye, (F) ileum, (G) lymph nodes, (H) pineal gland, (I) pituitary, (J) placenta, (K) proximal colon, (L) spinal cord, (M) spleen, (N) tonsil.'*

According to **Schedule 5, item 8, paragraph (g)** of the Regulations, sunscreen products are exempt from the operations of Parts 3-2 and 3-2A of the Act (and are therefore not required to be included in the ARTG) where they meet the following criteria:

'sunscreen preparations for dermal application, if:

- (i) the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:1998, as in force from time to time; and*
- (ii) the performance statements and markings on the label comply with that Standard; and*
- (iii) the sun protection factor stated on the label is less than 4, unless the preparations include ingredients of human origin, or of animal origin if the ingredient consists of, or is derived from, any of the following parts of cattle, sheep, goats or mule deer:*
 - (A) adrenal, (B) brain, (C) cerebro-spinal fluid, (D) dura mater, (E) eye, (F) ileum, (G) lymph nodes, (H) pineal gland, (I) pituitary, (J) placenta, (K) proximal colon, (L) spinal cord, (M) spleen, (N) tonsil.'*

According to **Schedule 7, item 14** of the Regulations, sunscreen products are exempt from the operation of Part 3-3 of the Act (and are therefore not required to be manufactured in accordance with the Code of Good Manufacturing Practice) unless supplied as pharmaceutical benefits where they meet the following criteria:

‘sunscreen preparations for dermal use that:

- (a) are packaged in containers the labels of which include a statement that the preparations have a sun protection factor below 4 or the equivalent category description; and*
- (b) when tested as described in Standard AS/NZS 2604:1998, as in force from time to time, are established to have a sun protection factor below 4 or the equivalent category description’*

Appendix 2: 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+.

AS 2604—1986 was referenced in Schedule 4, Part 1, item 7 and in Schedule 5 item 8, paragraph (g) of the original *Therapeutic Goods Regulations 1990*. Schedule 7, item 14 simply referred to “sunscreen preparations for dermal use” without referring to the Standard.

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. The Regulations were amended on 1 June 1994 by replacing “Australian Standard AS2604—1986 as amended and in force from time to time” with “Joint Standard AS/NZS 2604:1993 published by Standards Australia, as in force from time to time” in Schedule 4, Part 1, item 7 and in Schedule 5, item 8, paragraph (g). Schedule 7, item 14 was expanded to include labelling requirements and also a reference to testing as described in “Joint Standard AS/NZS 2604:1993 published by Standards Australia, as in force from time to time”.

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. The Regulations were amended on 18 December 1997 to adopt AS/NZS 2604:1997 by simply replacing “AS/NZS 2604:1993” with “AS/NZS 2604:1997” in Schedule 4, part 1, item 7 and Schedule 5, item 8, paragraph (g). The amendments became effective on gazettal. Schedule 7, item 14 continued to refer to AS/NZS 2604:1993.

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, and the Regulations were not amended to recognise this revision of the standard until 28 June 2001 when “AS/NZS 2604:1997” was simply replaced with “AS/NZS 2604:1998” in Schedule 4, part 1, item 7 and Schedule 5, item 8, paragraph (g). Schedule 7, item 14(b) was amended by replacing “Joint Standard AS/NZS 2604:1993, published by Standards Australia” with “Standard AS/NZS 2604:1998”.

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 resulting new Standard, AS/NZS 2604:2012, was published on 30 May 2012. It includes the following changes from AS/NZS 2604:1998:

- 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.
- Raising of the maximum Sun Protection Factor (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.
- 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.
- Making broad spectrum performance mandatory for all primary sunscreens and secondary sunscreens classified as ‘therapeutic sunscreens’ and regulated by the TGA.
- Making ‘broad spectrum’ either optional or mandatory for cosmetic sunscreens depending upon the nature of the product and the SPF claimed.
- Retaining the water resistance test procedure in AS/NZS 2604:1998 but replacing the test procedure for determining the SPF with that in ISO 2444:2010.
- Reducing the allowable claims for water resistance for sunscreens with SPF less than 30.

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