

Regulation Impact Statement

Proposed adoption of the *Australian/New Zealand Sunscreen Standard AS/NZS 2604:2012 Sunscreen products – Evaluation and classification by the Cosmetics Standard 2007*

National Industrial Chemicals Notification and Assessment Scheme

Department of Health and Ageing

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OBPR Reference 14146

Executive 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 sunscreen products (including face and nail and skin care products) must also comply with the *Cosmetics Standard 2007*, which draws on relevant aspects of the *Australian/New Zealand Sunscreen Standard AS/NZS 2604:1998 Sunscreen products – Evaluation and classification (the 1998 Sunscreen Standard)*. Cosmetic products are also regulated by the Australian Competition and Consumer Commission (ACCC) under the *Competition and Consumer Act 2010* in regard to product safety, and under the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991* for labelling.

Standards Australia and Standards New Zealand have revised and updated the 1998 Sunscreen Standard in consultation with all relevant stakeholders, and the new Standard was published in May 2012 as the *Australian/New Zealand Sunscreen Standard AS/NZS 2604:2012 Sunscreen products – Evaluation and classification (the 2012 Sunscreen Standard)*.

The Therapeutics Goods Administration (TGA) adopted the revised sunscreen standard for therapeutic sunscreen products by amendment of the *Therapeutic Goods Regulations 1990* in November 2012. Many businesses in Australia produce both cosmetic and therapeutic sunscreen products, and thus are regulated by both NICNAS and the TGA.

In relation to cosmetic sunscreen products, under the 1998 version of the Sunscreen Standard, cosmetic 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 actual allowed SPF that can be claimed is also limited by the *Cosmetics Standard 2007* (skin care products can have a maximum SPF of 15, and face/nail products the maximum claimed SPF as permitted under the sunscreen standard). The new Sunscreen Standard also sets more stringent requirements for broad spectrum performance and makes these mandatory for skin care products. The intention of these changes is to harmonise the AS/NZS Standard with international standards and to encourage the development and marketing of the most effective and beneficial cosmetic sunscreen products for face and nail and for skin care with a view to reducing the incidence of skin cancer in Australia and New Zealand.

Following consultation in December 2012-January 2013, NICNAS proposes to adopt the revised Sunscreen Standard for cosmetic sunscreen products by amending the *Cosmetics Standard 2007*. Consistent with cosmetic sunscreen products being secondary sunscreens as defined by the Sunscreen Standard, the primary function of these products is to provide a cosmetic benefit to consumers, with the sunscreen providing a secondary health benefit. Hence the main positive impact on stakeholders arising from the proposed adoption of the revised Sunscreen Standard is anticipated to be the increased business efficiencies and increased consumer confidence that will arise from both NICNAS and the TGA regulating their respective sunscreen products (cosmetic and therapeutic) against the same, 2012 version of the Sunscreen Standard. However, the extent of negative impacts arising from reformulating existing product lines to comply with the revised Sunscreen Standard, or

writing off existing product lines altogether, will be ameliorated by associated transitional arrangements whereby both the 1998 and 2012 versions of the Sunscreen Standard will be in force at the same time.

The TGA has adopted an open-ended transitional arrangement, whereby therapeutic sunscreen products that currently comply with the 1998 version of the Sunscreen Standard can legally remain for sale indefinitely, whilst new product lines must conform to the 2012 version of the Sunscreen Standard. This arrangement is based on the historical expectation that market forces will see a replacement of old product lines with new within the next two-three years. This is reinforced by the TGA's ability to efficiently monitor the introduction of new product lines into the market due to a requirement for sponsors to register their therapeutic sunscreen products on the Australian Register of Therapeutic Goods (ARTG).

However, due to the slower market dynamics of cosmetic sunscreen products as well as NICNAS not running a product registration system, NICNAS proposes the adoption of a five year, closed transition period. On this basis, NICNAS expects that adoption of the 2012 Sunscreen Standard would generally not require companies to reformulate their product lines ahead of the normal life-cycle of the product line, and will therefore generally result in only minor one-off costs to the cosmetic industry (estimated at \$300 per product due to the more stringent and expensive broad spectrum testing requirements of the 2012 Sunscreen Standard) incurred in developing, listing and launching products delivering safe and effective sun protection in cosmetic products and latest sunscreen innovations in these products. Businesses may also face extra reformulation costs of up to \$26,475 per product line in ensuring the cosmetic aesthetics, and therefore attractiveness to consumers, of their products are maintained. The closed transition period will also ensure a level playing field amongst businesses by requiring them to all comply with the revised Sunscreen Standard by the same date. Consumers may face increases in prices, but the increased consumer confidence of using the latest sunscreen innovations, combined with increased business efficiencies through working to a single Sunscreen Standard under both NICNAS and the TGA would, in the longer term, outweigh those cost increases.

The impacts to Government of NICNAS adopting the revised Sunscreen Standard for cosmetic sunscreen products will primarily relate to the need to train industry in the requirements of the revised standard. There would be no net increase in compliance work per se, as NICNAS currently assesses compliance against the 1998 Standard and would continue that work in relation to the 2012 standard. However, the nature of transitional arrangements will impact on compliance effort.

As NICNAS cannot easily monitor the introduction of new product lines in the market given the absence of a product registration system, it would be more effective for NICNAS to implement the transition period such that businesses can choose whether new product introduced during that period will initially comply with the 1998 or 2012 Sunscreen Standard, as long as all product complies with the 2012 Sunscreen Standard by the end of the transition period. This will avoid difficulties for NICNAS in distinguishing between existing and new product lines.

Moreover, NICNAS would commence compliance activities after the proposed, five-year transition period has closed and all products on the market must comply with the 2012 Sunscreen Standard. In contrast, an open transition period would mean that NICNAS would

need to check compliance against the two versions of the Sunscreen Standard on an indefinite basis, which would pose a significant impost on the organisation.

Preface

The crafting of a Regulatory Impact Statement (RIS) requires a clear delineation of the problem being addressed and the objective of any actions taken to address the problem. These two aspects, problem and objective, are closely intertwined. To assist the reader in understanding the relationship between the problem and objective as presented in this RIS, this Preface summarises these two aspects.

The objective behind the proposal that NICNAS adopt the 2012 Sunscreen Standard in relation to cosmetic sunscreen products is two-fold:

- to ensure that the performance characteristics of cosmetic sunscreen products, as established by the AS/NZ Sunscreen Standard, are consistent with those available elsewhere in what is a global market; and
- to ensure the consistent application of the latest available Sunscreen Standard for both cosmetic (regulated by NICNAS) and therapeutic (regulated by the TGA) sunscreen products in an industry where many businesses produce both cosmetic and therapeutic sunscreen products and therefore deal with the two regulators - and where consumers need to distinguish between the appropriate use of a cosmetic sunscreen product primarily for purposes of beautification, versus the appropriate use of a therapeutic sunscreen product primarily to protect against skin cancer caused through exposure to the sun's UV rays.

The problem that has arisen, and which requires action from NICNAS to ensure the above Objectives are maintained, is also two-fold:

- the 1998 version of the AS/NZ Sunscreen Standard currently brought into legal effect for cosmetic sunscreen products through the *Cosmetics Standard 2007* was replaced in May 2012 by a revised and improved version, hence NICNAS is currently enforcing an out-of-date standard that will limit community and business access to new innovations in sunscreen technology in Australia; and
- the TGA adopted the new, 2012 version of the Sunscreen Standard for therapeutic sunscreen products in November 2012, whereas NICNAS still administers the 1998 version of the Sunscreen Standard, thereby potentially causing inefficiencies for businesses that produce both cosmetic and therapeutic sunscreens and causing confusion for consumers.

1. Problem

1.1 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 skin cancer are diagnosed and treated annually in Australia.

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.

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 and effective, and that consumers have access to the latest sunscreen innovations in these products.

1.2 Regulation of Sunscreens in Australia

In Australia, sunscreens fall into two categories based on their function as delineated by the Sunscreen Standard (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")

- primary sunscreens (those used primarily for protection of all parts of the body from UV radiation) 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 sunscreensing) 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 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 Appendix 1.

1.3 The sunscreen market in Australia

NICNAS is uncertain of the overall number of businesses in the cosmetic sunscreen sector, which comprises multinational businesses that import product into, and formulate product in, Australia, and small domestic formulators which tend to use raw materials sourced locally. Increasingly important are major retail chains which import product directly. Responses to a December 2012 NICNAS survey that informed this RIS were mainly from multinational businesses and industry associations, and covered both importers and local manufacturers.

There are two main cosmetic sunscreen product types: skin care and face/colour products. A third category, nail products with sunscreen, is a very minor component. 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/colour and nail products, but anecdotal evidence from some businesses and from observation of product on the shelves suggests that skin care products represent the main portion of the market from a volume perspective, with face/colour being a not inconsiderable but smaller segment.

Cosmetic sunscreen products are regarded to be fast-moving consumer goods, but with a product life-cycle of 4-5 years for skin care and 5-7 years for face/colour product lines. These products also elicit considerable brand loyalty associated with consumer attraction to the cosmetic feel, rather than the sunscreen protection, afforded by the 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). The TGA

has observed that many product lines in the therapeutic sunscreen sector turn around every 2-3 years.

Many businesses operate in both the cosmetic and therapeutic sunscreen sectors – TGA data shows that some 50% of therapeutic sunscreen “sponsors” are also “registrants” with NICNAS. Moreover, the vast majority of respondents to the NICNAS survey deal with both cosmetic and therapeutic sunscreens. Furthermore, the formulations used in cosmetic and therapeutic skin-care sunscreen products, such as lotions, are quite similar. Hence, a significant portion of businesses in the cosmetic sunscreen market work to the Sunscreen Standard as administered by both NICNAS and the TGA.

1.4 References to the Sunscreen Standard in the *Cosmetics Standard 2007*

Cosmetic product categories in the *Cosmetics Standard 2007* must comply with the relevant sections of the Australian and New Zealand Sunscreen Standard (AS/NZS 2604:1998). See Appendix 2 for the full texts of the relevant items concerned.

The Sunscreen Standard 1998 (AS/NZS 2604:1998) is currently referenced as a ‘standard’ for face and nail, and for skin care products categories by 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.

While AS/NZS 2604 is a joint Australian and New Zealand Standard, it has not been adopted into law in New Zealand, where sunscreen products are all regulated as cosmetics. Hence, sunscreen products marketed in New Zealand do not have to comply with AS/NZS 2604. Consequently, cosmetic sunscreens products are already available for sale in New Zealand labelled with SPFs much higher than SPF 30+.

1.5 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 (Appendix 3). 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 (improved broad spectrum performance).

Hence, 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.

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.

1.6 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 *Cosmetics Standard 2007* still requires compliance with the old Sunscreen Standard (AS/NZS 2604:1998). In the meantime, the TGA adopted the 2012 Sunscreen Standard for therapeutic sunscreens in November 2012 (see section 1.7).

The following are the main changes in the 2012 Sunscreen Standard as compared with the old Sunscreen Standard 1998. Details of these changes are provided in Appendix 3:

- 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+. This only affects face/nail products due to the *Cosmetics Standard 2007* requiring this product category to comply with the SPF limits imposed by the Sunscreen Standard. However, the increase in allowable maximum SPF that may be claimed does not affect skin care products as the *Cosmetics Standard 2007* limits the allowable SPF that can be claimed to no more than 15.
- 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, and so this is optional for cosmetic skin care products regulated by NICNAS, which must have SPF no greater than 15. However, the 2012 Sunscreen Standard 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 affects all skin care products as broad spectrum performance is mandatory for these products regardless of claimable SPF, but only mandatorily affects face/nail products with claimed SPF of 30 or more as broad spectrum performance is only mandatory at the newly-allowed higher claimable SPF for this product type – it is optional for face/nail products with claimed SPF of less than 30.
- Enhanced broad spectrum performance requirements, whereby the degree of protection from UVA is 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+ face/nail sunscreen product complying with the 2012 Sunscreen Standard would provide 10 - 20 times the protection against UVA radiation provided by a typical SPF 30+ sunscreen complying with the old Sunscreen Standard 1998.
- The water resistant aspect of the 2012 Sunscreen Standard 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.

The 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.

In summary, the creation of the 2012 Sunscreen Standard has given rise to the first of a two-fold problem, namely that NICNAS is currently enforcing an out-of-date standard that will limit community and business access to new innovations in sunscreen technology in Australia. This is because the 1998 version of the AS/NZ Sunscreen Standard currently brought into legal effect for cosmetic sunscreen products through the NICNAS *Cosmetics Standard 2007* was replaced in May 2012 by a revised and improved version. Specifically,

and to the extent that cosmetic sunscreen products provide a health benefit as secondary sunscreens:

- under the 1998 Sunscreen Standard, cosmetic skin care sunscreen products can optionally adopt broad spectrum performance, whereas under the 2012 Sunscreen Standard, it is mandatory for these products to have broad spectrum performance; and
- under the 1998 Sunscreen Standard, cosmetic face/nail sunscreen products can only claim SPF 30+ (which does not provide an incentive to have an actual tested SPF of higher than 30) whereas under the 2012 Sunscreen Standard, such products can claim an SPF of 50+ (which provides an incentive to have an actual tested SPF of up to 60 (for a claimed SPF of 50+, the tested SPF must be 60 or higher)).

1.7 Adoption of the Revised Sunscreen Standard 2012 by the TGA and implications for cosmetic sunscreen products

As noted, primary sunscreens (those used primarily for protection of all parts of the body from UV radiation) 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. The TGA completed a RIS for this regulatory change in August 2012 (OBPR reference 13498).

Allowing sunscreens that comply with the old Sunscreen Standard (AS/NZS 2604:1998) to remain listed avoids major disruption of the supply of therapeutic 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.

Some industry stakeholders expressed an expectation that NICNAS would mirror the TGA approach by adopting the 2012 Sunscreen Standard and implementing an identical transition arrangement to minimise undue imposts on business. However, the practicality of such an arrangement needs to be considered in the context of the different regulatory frameworks for cosmetic and therapeutic sunscreen products.

As noted in the Preface, the adoption of the 2012 Sunscreen Standard by the TGA has given rise to the second of a two-fold problem, namely that the TGA adopted the new, 2012 version of the Sunscreen Standard for therapeutic sunscreen products in November 2012, whereas NICNAS still administers the 1998 version of the Sunscreen Standard. The enforcement of two significantly different versions of the Sunscreen Standard will potentially cause inefficiencies for businesses that produce both cosmetic and therapeutic sunscreens and cause confusion for consumers.

Inefficiencies could arise as businesses that are regulated by both NICNAS and the TGA will need to adopt different approaches for their cosmetic compared to therapeutic sunscreen product lines by:

- creating different labelling to meet the different statements permitted for similar product characteristics – for example, a face/nail cosmetic product with a claimed

SPF of at least 15 but less than 30 must be labelled as a “High protection sunscreen” under the 1998 version of the Sunscreen Standard (as currently enforced by NICNAS) whereas a therapeutic sunscreen product with the same claimed SPF must be labelled as “medium protection” or “Moderate protection” under the 2012 Sunscreen Standard newly enforced by the TGA – this can also cause confusion for consumers;

- addressing different broad spectrum performance requirements - for example, a face/nail cosmetic product with a claimed SPF of at least 15 must address the less stringent broad spectrum requirements of the 1998 Sunscreen Standard but a therapeutic sunscreen product with the same claimed SPF must now address the more stringent broad spectrum requirements of the 2012 Sunscreen Standard;
- cosmetic and therapeutic sunscreen products that wish to claim broad spectrum performance must utilise different testing methodologies as prescribed in the two versions of the Sunscreen Standard.

Consumers could also be confused by the appearance of incompatible SPF claims on the labels of face/nail cosmetic sunscreen products (which can currently claim SPF 30+) compared with therapeutic sunscreen products (which can claim SPF30, 40, 50 and 50+) – what does “30+” actually mean in this situation?

1.8 Understanding the different stakeholders for therapeutic and cosmetic sunscreens

Although industry has expressed a concern that NICNAS mirror the TGA in the adoption of the 2012 Sunscreen Standard, it is appropriate to note that there are two differences between the NICNAS and TGA systems that impact on the extent to which businesses are impacted by both regulators, as well as the ability of NICNAS to implement a transition system that mirrors that implemented by the TGA. These two differences relate to the concept of which business type is regulated, and to the registration of products.

Differences in the entity that is regulated

Not all businesses deal with both regulators. There are also differences in the concepts regarding which businesses are regulated by NICNAS and which by the TGA, so that certain businesses may not even intersect across the two regulators. NICNAS regulates “introducers” and the TGA regulates “sponsors”.

“Sponsor” in the TGA context is a person or company who does one or more of the following:

- exports therapeutic goods from Australia
- imports therapeutic goods into Australia
- manufactures therapeutic goods for supply in Australia or elsewhere
- arranges for another party to import, export or manufacture therapeutic goods.

A sponsor is responsible for applying to the TGA to have their therapeutic good included on the ARTG. In Australia, therapeutic goods must be included on the ARTG before they can be sold.

In contrast, only “introducers” of industrial chemicals need to be registered with NICNAS. “Introduction” relates to the importation or manufacture in Australia of an industrial chemical – the concept does not relate to products per se. Hence businesses in Australia that manufacture a cosmetic sunscreen product from domestically sourced chemicals do not need to be registered with NICNAS, whereas if they apply to list therapeutic sunscreen products on the ARTG, they would be sponsors under the TGA. However, manufacturers of cosmetic sunscreen products are required to comply with the *Cosmetics Standard 2007*, and hence the Sunscreen Standard.

NICNAS believes, based on its knowledge of the sector, that only a few, very small “mum and dad” businesses would be manufacturing cosmetic sunscreen products solely from domestic products.

Approximately 50% of sponsors of therapeutic sunscreen products under the TGA are also registered as introducers under NICNAS. The vast majority of respondents to the NICNAS consultation reported that they trade in both therapeutic and cosmetic sunscreen products – these included industry associations that represent a wide range of manufacturers, importers and retail businesses. Hence there is a significant overlap between the two groups of regulated entities, and certainly a significant number of major businesses trade in both the cosmetic and therapeutic sunscreen sectors in Australia, and hence interact with both regulators.

In contrast, NICNAS is not aware of how many introducers who trade in cosmetic sunscreen products do not also interact with the TGA – this is because NICNAS is not empowered under its legislation to collect information on the use of chemicals as part of the registration process.

Differences in product registration

Another significant difference between the two regulatory systems is that NICNAS does not maintain a register of cosmetic products, whereas the TGA maintains the ARTG. As a chemicals-based regulator, NICNAS is not empowered under its legislation to require businesses to register their products.

As a result, NICNAS does not hold comprehensive data on the numbers and types of cosmetic sunscreen products that are on the market, and therefore does not have data on which introducers are associated with which products. As a result, NICNAS also is unable to reliably track when a new product enters the market. In contrast, the TGA does have such data in relation to therapeutic sunscreen products, and can therefore reliably monitor compliance with its transitional arrangements whereby new therapeutic sunscreen product must comply with the requirements of the 2012 Sunscreen Standard.

In contrast, NICNAS can only seek data on the introduction of new cosmetic sunscreen products from industry on a voluntary basis, as well as monitoring products on the shelves through “shopping basket” surveys. This only enables NICNAS to obtain an indication of new product introductions. Moreover, even though businesses are required under the IC(NA) Act to comply with the *Cosmetics Standard 2007* (and hence the Sunscreen Standard as referenced therein), the lack of a legal requirement to register cosmetic sunscreen products with NICNAS also means that there is no definition of what constitutes a “new product” – hence a business may view a very minor modification to a product as not constituting the creation of a new product, and therefore the need to comply with the 2012 Sunscreen Standard could come into dispute.

2. Objectives

The *primary* objective of the regulation of cosmetics sunscreens in Australia by NICNAS as secondary sunscreen products is to ensure their efficacy in providing a limited sun protection benefit, which is subsidiary to their primary cosmetic role. Related to this is the need to ensure clarity in the market place, whereby these cosmetic sunscreen products should not be used instead of primary sunscreens when the desired result is to protect against sunburn and skin cancer.

A *secondary* objective of regulation of cosmetic sunscreen products 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. This objective is influenced by the fact that many businesses produce both therapeutic and cosmetic sunscreen products, and so deal with both regulators: some 50% of businesses that are sponsors of therapeutic sunscreen products under the TGA are registered with NICNAS as introducers of industrial chemicals.

As noted in the Problem section, these Objectives have been impacted by NICNAS currently enforcing an out-of-date Sunscreen Standard compared to those which are

observed internationally and that which the TGA is now enforcing for new therapeutic sunscreen products.

3. Options available to NICNAS

NICNAS proposes two options regarding adoption of the 2012 Sunscreen Standard in the *Cosmetics Standard 2007*, namely the status quo (Option 1), and its preferred option of adopting the 2012 Sunscreen Standard with a five year transition period (Option 2A). NICNAS also compares Option 2A against another option preferred by most (industry) respondents to the NICNAS survey, namely the adoption of the 2012 Sunscreen Standard with an open-ended transition period (Option 2B).

These various options are described in this section, along with their general consequences. Following a description in Section 4 of the consultation process and the main views of respondents obtained therefrom, the specific impacts arising from these options on stakeholders are described in Section 5.

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 with respect to cosmetic sunscreen products would have the following consequences:

- There will be a lack of consistency of application of the Sunscreen Standard with respect to new 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 (depending on whether a product is a therapeutic or cosmetic sunscreen product), resulting in inefficiencies for business and confusion among consumers.
- The 2012 Sunscreen Standard 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 2012 Sunscreen Standard, 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 2012 Sunscreen Standard, only because the government has not adopted the Sunscreen Standard at all. 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 2012 Sunscreen Standard were adopted in the *Cosmetics Standard 2007*, NICNAS would make only the minimum regulatory changes needed to give full effect to the 2012 Sunscreen Standard as applied to cosmetic sunscreen products, 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.

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 2012 Sunscreen Standard, with the consequent write-offs of existing stock or reformulation of existing product lines that comply with the 1998 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 by new product, as was the case with previous revisions of the Sunscreen Standard. The new products must comply immediately with the 2012 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 for face and nail products with SPF less than 30).

However, for cosmetic skin care products with SPF which is limited by the *Cosmetics Standard 2007* to 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 2012 Sunscreen Standard, 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 in the cosmetic sunscreen product sector. Hence, the two sub-options for possible transitional arrangements are proposed as follows:

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

In this option, manufacturers would have a finite period of time (five years) within which they must replace existing products that do not conform to the 2012 Sunscreen Standard with product that does. The five year period was derived from the results of consultation (where a 24 month transition period was proposed in the consultation, and views requested on other lengths of transition – various stakeholders requested the same or longer periods). Based on these views, NICNAS regards a five year period to be closer to the normal life-cycle of cosmetic sunscreen product lines (around 4-5 years for skin care products and 5-7 years for face/nail products), noting that industry is aware that a 2012 Sunscreen Standard has been under development for the last several years (see Appendices 3 and 4).

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 implementation where 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 importers to discontinue marketing of their cosmetic sunscreen products complying with the old Sunscreen Standard 1998 within a few years of adoption of the 2012 Sunscreen Standard, thereby delivering benefits to consumers and efficiencies to business in a reasonable timeframe.

4. Consultation

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 (Appendix 4), chaired by the Cancer Council of Australia. NICNAS, the TGA, and various industry and community stakeholders participated in the development of the 2012 Sunscreen Standard.

The new Standard was published as AS/NZS 2604:2012 on 30 May 2012. However, it has no legal force in Australia in regard to cosmetic sunscreen products until adopted in the *Cosmetics Standards 2007* and, until that happens, cosmetics sunscreen products must comply with the previous Standard AS/NZS 2604:1998.

In order to allow the Government to make a decision about adoption of the 2012 Sunscreen Standard for cosmetic sunscreens, NICNAS conducted a public consultation through the publication of a consultation paper and a 'Questionnaire' sheet on the NICNAS website. The consultation process ran from 4 December 2012 to 25 January 2013 and was advertised through notices in the NICNAS Chemical Gazette, the Australian Government Business website, and also on the Australian Government public consultation website.

The discussion paper incorporated the likely impacts of NICNAS adopting the 2012 Sunscreen Standard in relation to skin care products (which involve similar, though not identical, formulations to therapeutic sunscreen products), based on prior direct consultation with the TGA, key industry associations and measurement laboratories, and sought verification of these predictions. However, face and nail products with sunscreen involve significantly different formulations to both skin care products and therapeutic sunscreens, the impact of which NICNAS was not able to estimate through its initial, direct consultations. Therefore, the public discussion paper sought views on these impacts *de novo*.

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

NICNAS proposed in the public discussion that the 2012 Sunscreen Standard be adopted in relation to cosmetic sunscreen products. This proposal was based on NICNAS's views on the benefits of the 2012 Sunscreen Standard over the 1998 version developed through its involvement in the technical committee process, as well as the fact that the TGA had already adopted the 2012 Sunscreen Standard. This proposal included a transition period of two years, when cosmetic sunscreen products complying with both the 1998 and the 2012 versions of the Sunscreen Standard could be on the market, so as to reduce write-off and reformulation costs for business whilst minimising any consumer confusion.

The discussion paper also sought views on other options:

- what other lengths of transition would be appropriate that could reasonably minimise compliance costs for business whilst maintaining consumer confidence;
- whether an open-ended transition arrangement as adopted by the TGA would be appropriate (ie where current product lines can comply with the 1998 version and new product lines must comply with the 2012 version of the Sunscreen Standard, without any time limits being set); and
- whether the status quo should be maintained (ie 1998 version of the Sunscreen Standard should in fact be retained and the 2012 version not adopted for cosmetic sunscreen products).

A total of fourteen responses were received, with thirteen from industry (including three industry associations) and one from a community association. These fourteen responses all supported the adoption of the 2012 Sunscreen Standard. A summary analysis of results is at Appendix 5 and is also published on the NICNAS website.

The main difference of view expressed by stakeholders concerned the proposed transition period, during which both the current and revised Sunscreen Standards would be in force. The majority of responses (nine) were in favour of an 'open-ended' transition period, in which products complying with the current Sunscreen Standard could remain on the market indefinitely. In contrast, five responses preferred a fixed transition period of two to five years, after which time all products must comply with the 2012 Sunscreen Standard.

The reasons given by respondents for supporting an open-ended transition period were consistency with the TGA's application of their transitional arrangements, as well as avoiding significant write-off costs for industry by ensuring that the natural life-cycle of around five years finishes before product lines must be reformulated in compliance with the 2012 Sunscreen Standard .

However, NICNAS notes that:

- the TGA expects market forces to replace old therapeutic sunscreen products by new products within two-three years; and
- a closed transition arrangement of long enough duration can accommodate the concerns of industry concerning write-off costs, whilst providing a level playing field for all businesses to comply with the 2012 Sunscreen Standard by the same date and minimising costs to NICNAS of ensuring compliance against two versions of the Standard in effect at the same time.

- as NICNAS is not empowered to require registration of cosmetic sunscreen products, it cannot monitor the introduction of new products nor enforce a definition of what constitutes a new product for the purposes of compliance with the 2012 Sunscreen Standard.

5. Regulatory Impact Analysis of available options

5.1 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 2012 Sunscreen Standard, it will have the following main impact on different stakeholders:

Businesses:

- As the TGA has adopted the 2012 Sunscreen Standard, 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 50% of companies that sponsor therapeutic sunscreen products under the TGA are also registered with NICNAS – ie these companies are involved in marketing both therapeutic as well as cosmetic sunscreen products and would have to comply with two different versions of the Sunscreen Standard in Australia at the one time.
- Although Australian manufacturers will still be able to export cosmetic sunscreen product complying with the 2012 Sunscreen Standard to overseas markets (proportion of overall market unknown), it may be cost inhibitory as these companies will need to work to two sets of performance criteria (overseas requirements reflected by the 2012 Sunscreen Standard in relation to exports, and the 1998 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, to the extent that these secondary sunscreen products are designed to provide some protection over and above their primary function as cosmetics.

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 version of the 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.

5.2 Qualitative Impacts of Option 2 (adopt the revised Sunscreen Standard 2012)

Whilst noting the positive impacts of adopting the 2012 Sunscreen Standard as described in Section 3 Option 2, there will also be negative consequences.

Industry has noted the following specific impacts of adopting the 2012 Sunscreen Standard:

- re-testing to more stringent broad spectrum performance criteria using a new, internationally-harmonised testing method that is slightly more expensive for cosmetic sunscreen products that are mandated to have broad spectrum performance under the 2012 Sunscreen Standard (face/nail with SPF>30 and all skin care products with SPF) — this cannot be ameliorated by transitional arrangements;
- reformulation of cosmetic sunscreen products to meet the more stringent broad spectrum performance requirements may be required, noting:
 - for those cosmetic sunscreen products (including face and nail and skin care products) currently imported into Australia that already comply with the performance requirements of the 2012 Sunscreen Standard (reflecting the supply available overseas, proportion not known) reformulation would not be necessary;
 - for the few companies that have chosen not to include broad spectrum performance for skin care products, as allowed by the 1998 Sunscreen Standard (where such performance is optional), reformulation of their product lines will be required at significant cost as the 2012 Sunscreen Standard makes this performance requirement mandatory for skin care products - hence this impact would not be ameliorated by any transitional arrangement.
- as consumers tend to identify with a cosmetic sunscreen product in terms of the product's cosmetic aesthetic properties (texture, aroma etc) rather than its sunscreensing characteristics, any reformulation of the product line to accommodate the higher performance requirements of the 2012 Sunscreen Standard will likely involve significant reformulation challenges, and therefore costs, to maintain those cosmetic characteristics. This impact might be ameliorated by transitional arrangements of an appropriate length, depending on the extent of reformulation that a business would have undertaken anyway as a result of the current product life-cycle coming to an end and the extent of innovation in the new product line.

The direct negative impact on Government arising from the adoption of the 2012 Sunscreen Standard regardless of transition arrangements is relatively minor. As NICNAS currently

undertakes work to determine and correct business compliance with the current Sunscreen Standard, and this work will continue unchanged in relation to compliance with the 2012 Sunscreen Standard, there is no net impact on such work by NICNAS. However, NICNAS will need to undertake additional education and awareness-raising to ensure business and the community understands the changes.

Transitional arrangements

Transitional arrangements are the key to ameliorating avoidable compliance costs for industry being forced to adopt the 2012 Sunscreen Standard, as well as for NICNAS in ensuring compliance with that standard.

Industry has advised that its costs arise due to the need to both retest and reformulate products to comply with the 2012 Sunscreen Standard. Retesting using the more expensive methodology mandated by the 2012 Sunscreen Standard will be incurred regardless of transitional arrangements, but extra reformulation costs will be triggered if compliance against the revised Standard is required at a time point ahead of the natural product life cycle, when business would reformulate their product anyway. If compliance is required after the natural product life-cycle is complete, the same reformulation costs would be required regardless of whether the 2012 Sunscreen Standard was adopted or not – hence extra costs directly attributable to formulation against the 2012 Sunscreen Standard would not be incurred.

Additional NICNAS costs will arise to the extent that both standards might be in legal effect at the same time.

Option 2A: Adopt revised Sunscreen Standard 2012 and also allow currently marketed cosmetic sunscreen products complying with the 1998 Sunscreen Standard to remain in the market for another five years

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 five years. This would avoid 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 if the company is forced to reformulate the products outside the normal product cycle.
- Australian manufacturers will be able to develop and market sunscreen products both in Australia and overseas which comply with the 2012 Sunscreen Standard, and achieve economies of scale. Similarly, foreign manufacturers are likely to have already developed products complying with the 2012 Sunscreen Standard 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.
- All businesses would need to comply with the 2012 Sunscreen Standard by the same date (when the old Sunscreen Standard would no longer have legal effect), ensuring a level playing field thereafter. That is to say, businesses will then face the same mandatory performance, testing and labelling requirements, as well as having the same freedoms to choose to adopt any optional performance requirements.

Community:

The benefits to consumers accessing higher-performing cosmetic sunscreen products, complying with the 2012 Sunscreen Standard 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 five years transitional period for maintaining two versions of the Sunscreen Standard concurrently, and monitoring compliance with the changeover at the end of the transition period. However, the cost of monitoring compliance could be ameliorated by NICNAS choosing to undertake compliance monitoring at the close of the transition period, when all cosmetic sunscreen products must then comply with the 2012 Sunscreen Standard.

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

As products complying with the 2012 Sunscreen Standard become available, the marketability of cosmetic sunscreen products complying with the old Sunscreen Standard 1998 would decline. However this may be driven by supply considerations (as the supply of imported product complying with the 1998 Sunscreen Standard dries up) rather than demand considerations (as consumers may not discern a clear benefit of purchasing cosmetic sunscreen products complying with the 2012 Sunscreen Standard). Therefore, although it is expected that the availability of cosmetic sunscreen products complying with the old Sunscreen Standard 1998 will start declining soon after the adoption of the 2012 Sunscreen Standard, 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 five years which will create a level-playing field by requiring all businesses to comply with the 2012 Sunscreen Standard within a specified time, the indefinite transition period in Option 2B would have the additional impacts of potentially increasing the period in which both the 1998 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 indefinitely) 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 five year period).

The problem for NICNAS in administering both versions of the Sunscreen Standard indefinitely is also compounded by potential confusion over when does an existing cosmetic sunscreen product become new (and therefore need to comply with the revised Sunscreen Standard). As NICNAS does not run a product registration scheme, processes for determining such matters do not exist and much work would be likely required to establish a common understanding with industry and the community.

The above discussion on qualitative impacts can be summarised by categorising businesses into three groups in terms of potential impacts – quantitative costs for these groups are discussed in the next section.

Business group	Impact of complying with 1998 versus 2012 Sunscreen Standard	Impact of transitional arrangements
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<p>Group 1: intending to introduce a new product line regardless of any change to the Sunscreen Standard</p>	<p>As formulation of the new product is required <i>de novo</i> and would have occurred anyway, the difference in impact of complying with the 1998 or 2012 Sunscreen Standard relates only to the more stringent and expensive broad spectrum testing requirements</p>	<p>The extra cost of re-testing against the 2012 Sunscreen Standard will not be ameliorated by transitional arrangements as they must be incurred even if the business would have reformulated anyway</p>
<p>Group 2: remarketing of an existing cosmetic sunscreen formulation which already complies with the performance requirements of the 2012 Sunscreen Standard - for example a skin care product where a business has chosen to include the more stringent broad spectrum performance or higher SPF allowed overseas, but which cannot be claimed under the 1998 Sunscreen Standard</p>	<p>The formulation would need to be re-labelled as different SPF numbers and category descriptors are required for all products, and some product must also comply with mandatory broad spectrum requirements.</p> <p>Retesting would also be required as for Group 1.</p>	<p>The re-labelling costs will be ameliorated by transition arrangements where compliance with the 2012 Sunscreen Standard is required at a time after the product life-cycle finishes and therefore the business would have redeveloped the product anyway.</p> <p>The extra cost of re-testing against the 2012 Sunscreen Standard will not be ameliorated as noted for Group 1.</p>
<p>Group 3: remarketing of an existing cosmetic sunscreen product that currently does not comply with the performance requirements of the 2012 Sunscreen Standard – for example, where a business chose not to include broad spectrum performance in a skin care product but must do so under the 2012 Standard</p>	<p>The product would need to be reformulated, labelled and tested <i>de novo</i> under the 2012 Standard</p>	<p>As with Group 2, the impacts on relabelling and reformulation will be ameliorated where compliance with the 2012 Standard is mandated after the product life cycle finishes and so the product would have been labelled and reformulated anyway.</p> <p>The extra cost of re-testing would not be ameliorated by transitional arrangements, as for Group 1.</p>

Note:

- Certain new performance features enabled by the 2012 Sunscreen Standard in combination with the *Cosmetics Standard 2007*, such as ability to claim SPFs up to 50+ (for face/nail but not for skin care products) are optional rather than mandatory – in such cases, once a business chooses to incorporate such a feature, other businesses may be obliged to do likewise as a result of competitive pressure, but this then is a competition rather than regulatory impact.
- The extent of reformulation required of a product is not certain – even though the extent of reformulation required for a product already addressing the less stringent broad spectrum requirements of the 1998 Sunscreen Standard to enable it to meet the more stringent broad spectrum requirements of the 2012 Sunscreen Standard might seem relatively minor (involving adjustments in the combinations of current UV filter chemicals used), some businesses regard the extent of reformulation required as being major due to the technical challenges of ensuring the cosmetic aesthetics of the product are maintained – the extent of the extra impost also depends on the extent of innovation the business would have built into the new product line anyway.

5.3 Quantitative 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 – the groupings are as described above, and were originally tested for relevance (and found to be relevant) in the consultation document as “Scenarios”. Although these costs are based on skin care products as provided by testing laboratories, industry regards these costs as being similar for face/nail products, noting that the formulations are nonetheless quite different (lotion for the former; waxy stick, powder, liquid for the latter) and that optionally achieving higher SPF (from 30+ to 50+ for face/nail products) does not involve significant changes in the use of existing chemistry.

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

Companies in Group 1 are developing, testing and labelling a completely new cosmetic sunscreen (skin care) product with a SPF 15, complying with the 2012 Sunscreen Standard. The additional cost to industry would be about \$300 in once-off costs due to the need to test against more stringent broad spectrum performance requirements using a more advanced, internationally-harmonised test method (affected item highlighted). This cost would not be ameliorated by transitional arrangements (see below) as the business is choosing to introduce a new product anyway.

Tests		Associated costs under:	
		old Standard	revised Standard
Efficacy	<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
	Total	\$2,175	\$2,475
Formulation	Formulation	\$5,000	\$5,000
	Total	\$5,000	\$5,000
Stability	Stability Testing	\$7,000	\$7,000
	Analytical Validation	\$9,000	\$9,000
	Total	\$16,000	\$16,000
Label changes	Artwork	\$500	\$500
	On Pack Printing Screens	\$500	\$500
	Carton Printing Plates	\$2,000	\$2,000
	Total	\$3,000	\$3,000
Total		\$26,175	\$26,475

The above table does not include costs for any toxicity tests as these would be same for the old and the 2012 Sunscreen Standard and therefore are not relevant for the present discussion. Industry has confirmed that the de novo formulation costs associated with meeting more stringent broad spectrum requirements are essentially the same.

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

Group 2 assumes the reasonable case (based on industry information) that some current cosmetic sunscreen (including face and nail and skin care products) products will be able to meet the requirements of the 2012 Sunscreen Standard without any change in the formulation. It also assumes that companies will be able to sell their old stock with updated labels complying with the 2012 Sunscreen Standard 2012 or use the same formulation to repack with new labels complying with the 2012 Sunscreen Standard. The additional cost to industry (affected items highlighted) would be about \$3300 in once-off costs, comprising:

- \$300 in re-testing costs for broad spectrum performance; and
- \$3000 in creating new labels.

The relabelling costs would be ameliorated by transitional arrangements.

Tests		Associated costs under:	
		old Standard	revised Standard
Efficacy	<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
	Total	\$2,175	\$2,475
Label changes	Artwork	\$500	\$500
	On Pack Printing Screens	\$500	\$500
	Carton Printing Plates	\$2,000	\$2,000
	Total	\$3,000	\$3,000
Total		\$5,175	\$5,475

Group 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

Group 3 assumes that some current cosmetic sunscreen (skin care) products do not comply with the 2012 Sunscreen Standard and these products will be marketed with a change in formulation and other testings, to comply with the 2012 Sunscreen Standard. However, advice from industry notes that such reformulation would be no

more expensive than formulating against the 1998 Sunscreen Standard. The additional cost to industry would be about \$26,475 in once-off costs (the entire cost of reformulation, testing and labelling) and would be ameliorated by transitional arrangements (affected items highlighted).

This same impact applies to the few businesses that chose not to include broad spectrum performance in skin care products under the 1998 Sunscreen Standard (where it is optional) but are mandated to do so under the 2012 Sunscreen Standard.

Tests		Associated costs under:	
		old Standard	revised Standard
Efficacy	<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
	Total	\$2,175	\$2,475
Formulation	Formulation	\$5,000	\$5,000
	Total	\$5,000	\$5,000
Stability	Stability Testing	\$7,000	\$7,000
	Analytical Validation	\$9,000	\$9,000
	Total	\$16,000	\$16,000
Label changes	Artwork	\$500	\$500
	On Pack Printing Screens	\$500	\$500
	Carton Printing Plates	\$2,000	\$2,000
	Total	\$3,000	\$3,000
Total		\$26,175	\$26,475

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

These groupings indicate the following impacts:

- A common underlying extra cost of \$300 associated with the need to retest against the more up-to-date, internationally harmonised test procedure in the International Standard (ISO 24443:2012) for determining the more strenuous broad spectrum performance. This procedure requires the degree of protection from UVA to increase with increasing SPF and is more expensive than the broad spectrum test procedure in the old Sunscreen Standard (AS/NZS 2604:1998).
- The additional cost for businesses that are already complying with the performance requirements of the 2012 Sunscreen Standard (by importing advanced product) but that need to relabel and retest would be around \$3300.
- Advice from industry notes that some companies who have chosen not to include broad spectrum performance in their skin care products (as allowed under the 1998 Sunscreen

Standard) will need to change formulation to meet the mandatory broad spectrum requirements under the 2012 Sunscreen Standard. In this case, the cost is estimated to be that of the absolute figure in Table 3 for complying with the 2012 Sunscreen Standard, namely around \$26,475 per product line.

- Industry also notes that the reformulation of cosmetic sunscreen products necessary to preserve the cosmetic aesthetics valued by consumers whilst providing the improved suncreening performance characteristics available under the 2012 Sunscreen Standard would cost somewhere between the net reformulation cost of \$300 per product line in Table 3 and the absolute cost of \$26,475.
- Whilst industry did not provide information on any likely price increases for consumers arising from the above cost imposts, the TGA has noted in its August 2012 RIS concerning its adoption of the 2012 Sunscreen Standard for therapeutic sunscreen products that there would likely be an increase of 15% to 30% in pricing, particularly for higher SPF products. It is not clear how these price increases would extrapolate to the cosmetics sunscreen product sector, noting:
 - the market for cosmetic sunscreen products is around 1/6th that of the therapeutic sunscreen market (Section 1.3 on the sunscreen market in Australia) and so there is a smaller base within which to absorb cost increases; however
 - consumer product loyalty hinges on the aesthetic features of the cosmetic sunscreen product rather than the improved sun protection afforded, and therefore consumers may not value the performance improvements the product affords relative to a price increase calculated to fully recover the cost increase; and
 - as New Zealand has not adopted AS/NZS 2604, there is no information available on comparable price changes

Overall impact of whether transition arrangements with a long enough period are implemented on costs for industry concerned with skin care product, following adoption of the revised Sunscreen Standard 2012 by NICNAS

Industry has advised that the product life cycle for a skin care product is 4-5 years, and for a face/colour product is 5-7 years. As already noted, the key impact of transitional arrangements on costs is whether the period of transition is longer than the product life cycle (industry preferred an open-ended transition – Option 2B) when presented with a relatively short transition period of 2 years in the consultation document (previous Option 2A, which NICNAS is now proposing to be five years to ensure reformulation is not required before the product life-cycle is complete).

Hence, the costs identified with the adoption of the 2012 Sunscreen Standard for the three groups of business would be ameliorated as follows depending on whether no, or a too short, transition period is adopted, compared to whether a long enough (open or closed) transition period is adopted.

Group	Transition period less than product life cycle (no transition period or previous Option 2A period of 2 years)	Transition period longer than product life cycle (revised Option 2A transition period of 5 years, or Option 2B open transition period)
Group 1 (introducing new product anyway)	\$300 in re-testing costs	\$300 in extra re-testing costs
Group 2 (remarketing an existing product with performance that complies with the 2012 Standard)	\$3300 in retesting and relabelling costs	\$300 in extra retesting costs – relabelling costs will be expended when business reformulates of its own accord
Group 3 (complete redesign of existing product as performance does not comply with 2012 Sunscreen Standard)	\$300-26,475 in retesting, relabelling and reformulating costs	\$300 in extra retesting costs – relabelling and reformulation costs will be expended when business reformulates of its own accord

However, it is again noted that:

- regardless of transitional arrangements, adoption of the revised Sunscreen Standard would likely present some reformulation challenges to maintain the cosmetic aesthetics of the product, with extra costs likely to be between \$300 and around \$26,475, depending on the extent to which the product would have been reformulated anyway.
- regardless of transitional arrangements, the few companies who chose not to incorporate broad spectrum performance in their cosmetic sunscreen products under the 1998 Sunscreen Standard, will incur a once-off cost of around \$26,475 per product line to reformulate against the mandatory broad spectrum performance requirements imposed by the 2012 Sunscreen Standard;
- adoption of a five year closed transition period will provide a level playing field whereby all businesses must comply with the 2012 Sunscreen Standard by the same date, thereby ensuring costs to industry are on a competitive footing;
- adoption of the five year closed and of the open-ended transition period will both ensure that product-lines will reach the end of their natural life cycle and so will be reformulated anyway before compliance with the 2012 Sunscreen Standard becomes mandatory. This will minimise write-off of old stock.

5.4 Overall impact of the NICNAS-preferred Option 2A

As outlined above, adoption of the 2012 Sunscreen Standard with a five year transition period for cosmetic sunscreen products would result in benefits to industry of complying with the same and latest version of the Sunscreen Standard across both NICNAS and the TGA, with compliance for cosmetic sunscreen products required by all business by the same date (level playing field).

There will be some one-off costs for industry which can be categorised in three ways based on why they are incurred:

- the extra cost of \$300 associated with retesting against the more expensive and stringent broad spectrum test requirements of the 2012 Sunscreen Standard – this extra cost will not be ameliorated by transition arrangements;
- the extra cost of maintaining the cosmetic aesthetics of the product, which in some cases, could be as high as \$26,475 depending on whether the reformulation is associated with changing sunscreens performance mandated by the 2012 Sunscreen Standard; and
- the same once-off costs of around \$26,475 would be incurred if business had chosen that their existing skin-care products would not meet the optional broad spectrum requirements of the 1998 Sunscreen Standard – they will then be non-compliant with the 2012 Sunscreen Standard and will need to be reformulated. However, NICNAS understands from industry that such cases are rare.

These extra costs will likely be off-set by 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, even if they are used as secondary sunscreen products. There will also be consistency with the TGA and other developed countries in the adoption of the 2012 Sunscreen Standard, and hence, reduced confusion for consumers.

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. NICNAS has played an active role in that revision process, and has ensured that any changes are in harmony with current legislative requirements for cosmetic sunscreens and with Government health policies.

NICNAS 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 benefits to consumers accessing cosmetic sunscreen products complying with the 2012 Sunscreen Standard include improved 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, and by raising the maximum claimed SPF from 30+ to 50+ for face and nail products; and enhanced 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. The benefits to industry include access to the latest innovations in sunscreen technology within the performance delineations of the *Cosmetics Standard 2007*, as well as efficiencies gained by complying with the same, latest version of the Sunscreen Standard across cosmetic and therapeutic sunscreen products.

Industry is concerned that the 2012 Sunscreen Standard be adopted in such a way that industry would not be forced to bear undue costs, such as would occur if business was forced to reformulate cosmetic sunscreen product over a two year period before the natural product life-cycle of 4-7 years expired and the product would be reformulated anyway. On this basis, industry did not support a closed transition period, but instead preferred an open-ended one, analogous to that adopted by the TGA in relation to the adoption of the 2012 Sunscreen Standard for therapeutic sunscreen products. Under the TGA transitional arrangements, existing product can continue to comply with the 1998 Sunscreen Standard indefinitely, and only new product need comply with the 2012 Sunscreen Standard. However, NICNAS does not run a product registration scheme and so cannot readily differentiate or check compliance of current and new products. Moreover, NICNAS is of the view that industry's concerns can be addressed by a closed transition period that is of a long enough length to accommodate the product life cycle. On this basis, NICNAS proposes a five year transition period, during which time both the 1998 and 2012 Sunscreen Standards would be in force, and after which time, only the 2012 Sunscreen Standard would be in force.

Allowing sunscreens that comply with AS/NZS 2604:1998 (but not with AS/NZS 2604:2012) during a five year transition period to remain available in the Australian market would avoid major disruption of the supply of cosmetic sunscreen products in Australia or write-off of existing stock. It would also allow the cosmetic industry time to bring their product ranges into line with the 2012 Sunscreen Standard to create a level-playing field by requiring all businesses to comply with the 2012 Sunscreen Standard within a specified time. In addition, it would provide certainty for consumers in only having one version of the sunscreen standard in place after the transition and also reduce the impost on NICNAS to concurrently audit cosmetic sunscreen products against two standards indefinitely.

If adopted in the *Cosmetics Standard 2007*, the 2012 Sunscreen Standard would be applicable to all cosmetic sunscreen products regulated by NICNAS.

7. Implementation

If a decision is made by Government to adopt the revised Sunscreen Standard (AS/NZS 2604:2012), NICNAS will initiate a process to amend the *Cosmetics Standard 2007* to recognise the 2012 Sunscreen Standard as soon as possible. The amended *Cosmetics Standard 2007* will be registered on the Federal Register of Legislative Instruments and published through the Chemical Gazette, as required by the IC(NA) Act. NICNAS also intends that the amendments commence immediately.

Amendments to the *Cosmetics Standard 2007* following the proposed adoption of the 2012 Sunscreen Standard by NICNAS would include the following (see Appendix 2 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.

NICNAS proposes to implement the five-year transition period by allowing industry to choose whether new cosmetic sunscreen product lines will initially comply with the 2012 Sunscreen Standard or the 1998 Sunscreen Standard, as long as all product lines comply with the 2012 Sunscreen Standard after the five year transition period is complete. This approach, rather than requiring new product lines to comply immediately with the 2012 Sunscreen Standard, would avoid the problem of potential disputes as to what is a current or new product line, given that NICNAS does not require the registration of cosmetic sunscreen products under its legislation.

NICNAS will then need to instigate compliance oversight to ensure the appropriate changeover of cosmetic sunscreen products to the 2012 Sunscreen Standard following any

designated transition period, and will seek the assistance of stakeholders in promulgating these changes throughout the market.

Appendix 1: 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"> - Moisturisers with sunscreen if SPF is 15 or less - Sunbathing products with SPF between 4 and 15 - Lip balms/lip sticks with sunscreen - “Make-up” products with sunscreen 	<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"> • Must comply with the <i>IC(NA) Act</i> and the <i>Cosmetics Standard 2007</i> which includes references to AS/NZS 2604:1998 • Labelling must comply with the relevant consumer and cosmetics legislation • Not required to be registered or listed in a database maintained by a regulatory authority 	<p>Requirements :</p> <ul style="list-style-type: none"> • Must comply with AS/NZS 2604:2012 • 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 <p>Companies pay application fees for listing/registration and annual charges</p>

Appendix 2: 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 secondary sunscreen product in AS/NZS 2604:1998; 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 AS/NZS 2604:1998</p>
2	Skin care	<p>a. Moisturising products with sunscreen for dermal application, including anti-wrinkle, anti-ageing and skin whitening products</p> <p>b. 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 secondary sunscreen product in AS/NZS 2604:1998;</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 broad-spectrum product set out in clause 7.2 of AS/NZS 2604:1998;</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 AS/NZS 2604:1998</p>

Appendix 3: 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.

Appendix 4: Consultation on the Sunscreen Standard 2012

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.

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, NICNAS 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.¹

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.

¹ 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>

**Appendix 5: NICNAS Consultation on the Sunscreen Standard
2012**



Australian Government
Department of Health and Ageing
NICNAS

National Industrial Chemicals Notification and Assessment Scheme

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

Consultation process and summary of outcomes – March 2013

About this report

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

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

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

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

Background to the consultation

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

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

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

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

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

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

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

Consultation process

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

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

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

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

Results

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

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

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

<p>Preference for Option 2B (adopt revised Sunscreen Standard 2012 with an open-ended transition period)</p> <p>The majority of responses (nine responses) were in favour of the adoption of the revised Sunscreen Standard 2012 with an open-ended transition period while four responses were against this option.</p> <p>The main reasons were: consistency with the TGA implementation approach of the revised Sunscreen Standard 2012; consumers would drive the take up of new product; and a closed transition period of 2-4 years would not provide sufficient time for transition and would result in significant write-off costs for companies, as the usual maximum expiry date or cosmetic sunscreens is about three years and orderly clearance of stock will also take about three years.</p> <p>The main reasons against this option were: the consumer has the right to expect certainty that only products complying with the revised Sunscreen Standard will be available to consumers; that cosmetic sunscreen products will meet the same Standard as therapeutic sunscreen products; difficulty for the regulator in tracking take up of the revised Sunscreen Standard; and the lack of a level playing field amongst businesses should there be no mandated requirement for products to stop conforming to the 1998 Sunscreen Standard.</p>	<p>As with Option 2A, NICNAS observes that the reasons for supporting adoption of the revised Sunscreen Standard in Option 2B were the same reasons for lack of support for retaining the current Standard.</p> <p>As NICNAS commented in the consultation paper, the regulator will face difficulties in tracking the adoption of the revised Sunscreen Standard in an open-ended transition arrangement due to a lack of a product register.</p> <p>It is also noted that the TGA has adopted an open-ended transition period in the expectation that new product complying with the revised Sunscreen Standard will replace product complying with the 1998 Standard within a period of two-three years.</p>
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Summary of Consultation Responses on Regulatory Impacts of NICNAS Proposal to Adopt the Revised Australian/New Zealand Sunscreen Standard 2012 for Cosmetic Sunscreen Products

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

not achieved for cosmetic sunscreens by adoption of an open transition period whereby there will be no mandated requirement for businesses to stop complying with the 1998 Sunscreen Standard.	
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Summary of Consultation Responses on Regulatory Impacts of NICNAS Proposal to Adopt the Revised Australian/New Zealand Sunscreen Standard 2012 for Cosmetic Sunscreen Products

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

