

EXPLANATORY STATEMENT

Issued by the authority of the Parliamentary Secretary for Health and Ageing

Industrial Chemicals (Notification and Assessment) Act 1989

Cosmetics Amendment (Sunscreen) Standard 2013

The *Industrial Chemicals (Notification and Assessment) Act 1989* (the ICNA Act) establishes a system of notification and assessment of industrial chemicals to protect health, safety and the environment, and to provide for registration of certain persons proposing to introduce industrial chemicals.

Subsection 81(1) of the ICNA Act enables the determination of standards for certain cosmetics, including skin care products containing sunscreen, antibacterial skin products, anti-acne products, anti-dandruff products and products for care of the teeth and mouth, imported into or manufactured in Australia having regard to Australia's International obligations. Currently there are no international treaties to which Australia is a signatory that cover cosmetics. While Australia is signatory to the Rotterdam and Stockholm Conventions that restrict trade in certain hazardous chemicals, no chemicals used in cosmetics in Australia are listed under either of these treaties. Section 81A establishes an offence for failure to comply with the any relevant cosmetics standards.

The *Cosmetics Standard 2007*, which sets the performance standards for six cosmetic categories, is made under section 81(1) of the ICNA Act and is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The purpose of the Amendment Standard is to amend the *Cosmetics Standard 2007* to adopt the newly published Sunscreen Standard, *AS/NZS 2604:2012 Sunscreen products—Evaluation and classification* (the 2012 Sunscreen Standard), which replaces the earlier Sunscreens Standard, *AS/NZS 2604:1998 Sunscreen products—Evaluation and classification* (the 1998 Sunscreen Standard), as an important benchmark for sunscreen products under the *Cosmetics Standard 2007*.

After consultation with a range of stakeholders including Accord, Cancer Council Australia, the TGA and NICNAS, Standards Australia and Standards New Zealand replaced the 1998 Sunscreen Standard with the 2012 Sunscreen Standard in May 2012. The 2012 Sunscreen Standard allows claims of sun protection factor (SPF) of up to 50+ to be made in relation to sunscreen products, as opposed to maximum claims of only 30+ under the 1998 Sunscreen Standard. The 2012 Sunscreen Standard also sets out a number of changes, in particular, to labelling requirements.

Under the revised *Cosmetics Standard 2007* which will commence from 1 August 2013, two categories of cosmetic sunscreen products (face/nail and skin care) will have five years within which to fully comply with the 2012 Sunscreen Standard. That is, these products must comply with specified aspects of the 1998 Sunscreen Standard or the 2012 Sunscreen Standard from 1 August 2013 to 31 July 2018. These products must then comply only with the 2012 Sunscreen Standard from 1 August 2018.

Details of the *Cosmetics Amendment (Sunscreen) Standard 2013* are listed in [Attachment A](#).

The Amendment Standard is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Amendment Standard commences on 1 August 2013.

NICNAS conducted consultation with industry and community stakeholders on a proposal to adopt the 2012 Sunscreen Standard for cosmetic sunscreen products with a two year transition period, whilst seeking views on alternative transition arrangements and on maintaining the status quo.

A total of fourteen responses were received, with thirteen from industry (including three industry associations) and one from a community association. These responses all supported the adoption of the revised Sunscreen Standard. 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 revised Sunscreen Standard. The preference for an open-ended transition period arose from a concern that businesses not be compelled to reformulate their product lines to comply with the requirements of the 2012 Sunscreen Standard ahead of the natural life-cycle of the products, thereby incurring unnecessary compliance costs. Following further discussions with stakeholders, NICNAS has ascertained that a five year transition period would be long enough to avoid the premature reformulation of product and therefore unnecessary compliance costs.

A Regulation Impact Statement (RIS) has been prepared in relation to proposed amendments to the *Cosmetics Standard 2007* to adopt the 2012 Sunscreen Standard with a five-year transition period, as well as other, less-preferred options. The Office of Best Practice Regulation has certified that the RIS (OBPR ref: 14146) in Attachment B contains adequate of analysis and meets the Government's best practice regulation requirements.

NOTES ON CLAUSES

Section 1 – This standard may be cited as the *Cosmetics Amendment (Sunscreen) Standard 2013*.

Section 2 – This standard commences on 1 August 2013.

Section 3 – This standard is made under subsection 81(1) of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

Section 4 – Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendments

Item 1 – Section 3

This item sets definitions of terms used in the Cosmetics Standard. Definition is added for the following term:

AS/NZS 2604:2012 means *AS/NZS 2604:2012 Sunscreen products—Evaluation and classification*, published by SAI Global on 30 May 2012.

This amendment therefore allows cosmetic sunscreen products to comply with either the requirements in the 2012 Sunscreen Standard, or the requirements of the 1998 Sunscreen Standard during the five year transition period.

Item 2 – Schedule 1 (cell at table item 1, column headed “Standards”)

The Schedule sets out the amendments for two types of cosmetics.

Face and Nail

Item 2 describes the requirements for tinted bases/foundation (liquids, pastes, powders) with sunscreen and also for products intended for application to the lips with sunscreen during and after the five year transition period.

The Cosmetics Standard requires that such a product imported into, or manufactured in, Australia before 1 August 2018 must:

- be a ‘secondary sunscreen product’ as defined in AS/NZS 2604:1998 or AS/NZS 2604:2012. AS/NZS 2604:1998 or AS/NZS 2604:2012 defines secondary sunscreen product as a sunscreen product which is represented on the label as protecting the skin from certain harmful effects of the sun’s rays while fulfilling another primary function. In essence, the product must contain a sunscreen for a secondary purpose only; and
- if the product states an SPF or equivalent category description on the label, the SPF or equivalent category description on the label must meet the requirements of clauses 6.2 and 6.3 of AS/NZS 2604:1998 or clauses 5 and 6 of AS/NZS2604:2012.

The Cosmetics Standard requires that such a product imported into, or manufactured in, Australia on or after 1 August 2018 must:

- be a ‘secondary sunscreen product’ as defined in AS/NZS 2604:2012. AS/NZS 2604:2012 defines secondary sunscreen product as a sunscreen product which is represented on the label as protecting the skin from certain harmful effects of the sun’s rays while fulfilling another primary function. In essence, the product must contain a sunscreen for a secondary purpose only; and

- if the product states an SPF or equivalent category description on the label, the SPF or equivalent category description on the label must meet the requirements of clauses 5 and 6 of AS/NZS2604:2012; 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; and
- the product must meet the performance requirements for a broad-spectrum product set out in both Table 1 in clause 5.2 of AS/NZS 2604:2012 and clause 6.3 of AS/NZS 2604.2012.

Item 3 – Schedule 1 (cell at table item 2, column headed “Standards”)

Skin care

This item sets out the requirements relating to moisturising products with sunscreen for dermal application (including but not limited to anti-wrinkle, anti-ageing and skin whitening products) and sunbathing products with SPF ≥ 4 and ≤ 15 (such as oils, creams, gels, including products for tanning without sun and after sun care products) during and after the five year transition period.

The Cosmetics Standard requires that such a product imported into, or manufactured in, Australia before 1 August 2018 must:

- be a ‘secondary sunscreen product’ as defined in AS/NZS 2604:1998 or AS/NZS 2604:2012. As noted in relation to item 1, AS/NZS 2604:1998 or AS/NZS 2604:2012 defines secondary sunscreen product as a sunscreen product which is represented on the label as protecting the skin from certain harmful effects of the sun’s rays while fulfilling another primary function;
- not be presented as having SPF > 15;
- if the product states an SPF or equivalent category description on the label, the SPF or equivalent category description on the label must meet the requirements of clauses 6.2 and 6.3 of AS/NZS 2604:1998 or clauses 5 and 6 of AS/NZS 2604:2012.;
- not be presented as being water-resistant;
- include an expiry date or use-by date on the label if the product is not stable for at least 36 months;
- have a pack size that does not exceed 300 mL or 300g;
- not have a therapeutic claim made in relation to the product, including any representation about skin cancer; and
- only make representations about premature skin ageing linked to sun exposure, if the product meets the performance requirements for a “broad-spectrum product” in clause 7.2 of AS/NZS 2604:1998 or both Table 1 in clause 5.2 of AS/NZS 2604:2012 and clause 6.3 of AS/NZS 2604:2012.

The Cosmetics Standard requires that such a product imported into, or manufactured in, Australia on or after 1 August 2018 must:

- be a ‘secondary sunscreen product’ as defined in AS/NZS 2604:2012. As noted in relation to item 1, AS/NZS 2604:2012 defines secondary sunscreen product as a sunscreen product which is represented on the label as protecting the skin from certain harmful effects of the sun’s rays while fulfilling another primary function;
- not be presented as having SPF > 15;
- if the product states an SPF or equivalent category description on the label, the SPF or equivalent category description on the label must meet the requirements of clauses 5 and 6 of AS/NZS 2604:2012.;
- not be presented as being water-resistant;
- include an expiry date or use-by date on the label if the product is not stable for at least 36 months;
- have a pack size that does not exceed 300 mL or 300g;

- not have a therapeutic claim made in relation to the product, including any representation about skin cancer; and
- the product must meet the performance requirements for a “broad-spectrum product” set out in:
 - (i) Table 1 in clause 5.2 of AS/NZS 2604:2012; and
 - (ii) clause 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.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Cosmetics Amendment (Sunscreen) Standard 2013

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The *Cosmetics Amendment (Sunscreen) Standard 2013* is made under section 81 of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

The purpose of the Amendment Instrument is to amend the *Cosmetics standard 2007* to, principally, adopt the *Sunscreens Standard 2604:2012* (the *Sunscreen Standard 2012*), published by Standards Australia and Standards New Zealand in May 2012, as an important benchmark for cosmetic sunscreens products from 1 August 2013, while permitting cosmetic sunscreens products to continue to rely on the *Sunscreens Standard AS/NZS 2604:1998* (the *Sunscreen Standard 1998*) until 1 August 2018.

Human rights implications

This amendment instrument will not have any impacts on human right as it simply specifies improved performance requirements for cosmetic sunscreen products in terms of their sun protection effect. These products are defined as secondary sunscreens whereby their primary role is as a cosmetic, and their sunscreen protection function is secondary.

The amendment instrument does not engage any of the applicable rights or freedoms.

Conclusion

This amendment instrument is compatible with human rights as it does not raise any human rights issues.

The Honourable Shayne Neumann

Parliamentary Secretary for Health and Ageing