Attachment 2

EXPLANATORY STATEMENT

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

Industrial Chemicals (Notification and Assessment) Act 1989

Cosmetics Standard 2007

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 allows the Minister to determine standards for cosmetics 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.

The Cosmetics Standard 2007 (the Cosmetics Standard) is made under subsection 81(1) of the ICNA Act and is a legislative instrument for the purposes of the Legislative Instruments Act 2003.

Background

On 20 August 2007, the *Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Act 2007* received Royal Assent. This legislation amended the ICNA Act to provide legislative underpinning for reforms to the regulation of cosmetics as part of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Low Regulatory Concern Chemicals Reform Program.

While the ingredients in cosmetics had been regulated by NICNAS as industrial chemicals for quite some time, the amending legislation represented an extension of the existing approach by enabling the relevant Minister to make standards, by legislative instrument, for cosmetic products as a whole that are imported into, or manufactured in, Australia.

The Cosmetics Standard is based on the requirements detailed in administrative arrangements which have been in place since 2006 (and have been reflected in the NICNAS Cosmetics Guidelines). These administrative guidelines will be updated to reflect the new legislative environment including the making of the Cosmetics Standard.

It is important to note that the requirements in the Cosmetics Standard are not the only requirements applying to cosmetics. For example, the product must also have full ingredient disclosure in accordance with the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991* and the product must not contain chemicals prohibited for use in cosmetics (or the product must meet any restrictions specified for chemicals used in cosmetics).

Further detail about the full set of regulatory requirements for cosmetics is included in the NICNAS Cosmetics Guidelines 2007.

Consultation

Prior to the introduction of the *Industrial Chemicals* (*Notification and Assessment*) Amendment (*Cosmetics*) Act 2007, NICNAS consulted with a broad range of stakeholders regarding the proposed changes including the proposed approach to the making of cosmetics standards. Consultation was conducted over a number of years with the cosmetics industry and its industry bodies, government and non-government organisations and worker and community representatives. All stakeholders broadly supported the implementation of standards for cosmetics.

In addition, the content of the Cosmetics Standard has been discussed with key industry and Government stakeholders. There is general agreement to the proposed approach, as reflected in the Cosmetics Standard.

Regulation Impact Statement

A Regulation Impact Statement (RIS) was prepared in relation to the *Industrial Chemicals* (*Notification and Assessment*) *Amendment (Cosmetics) Act 2007* which amended the ICNA Act to include the power to make standards. This RIS is available in the Explanatory Memorandum to that Act.

In accordance with Australian Government regulatory impact analysis requirements, NICNAS has conducted a preliminary regulatory assessment and self assessed that there are no impacts on business and individuals or the economy as a result of the Cosmetics Standard. As a result no further regulatory analysis will be undertaken.

Details of the Cosmetics Standard are listed at <u>Attachment A</u>.

NOTES ON CLAUSES

Clause 1 states that the name of the Standard is the Cosmetics Standard 2007.

Clause 2 states that the Standard commences on the commencement of Schedule 1 to the *Industrial Chemicals (Notification and Assessment) Amendment (Cosmetics) Act 2007.* This Act commences 28 days after Royal Assent. Royal Assent occurred on 20 August 2007.

Clause 3 sets out definitions of terms used in the Cosmetics Standard. Definitions are provided for the following terms:

- Act means the Industrial Chemicals Notification and Assessment Act 1989.
- *AS/NZS 2604:1998* means AS/NZS 2604:1998 Sunscreen products- Evaluation and classification, published by SAI Global, as existing when this Standard commences. A copy of AS/NZS 2604:1998 is available from NICNAS (free-of-charge).

Clause 4 provides that a cosmetic of a product category and type mentioned in Schedule 1 must comply with the standards mentioned for the product category and product type.

Schedule 1 Standards

The Schedule sets out the standards for various types of cosmetics.

Item 1 Face and Nail

Item 1 describes the requirements for tinted bases/foundation (liquids, pastes, powders) with sunscreen and also for products intended for application to the lips with sunscreen.

The Cosmetics Standard requires that such a product must:

- be a 'secondary sunscreen product' as defined in AS/NZS 2604:1998. AS/NZS 2604:1998 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.

Item 2 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 \geq 4 and \leq 15 (such as oils, creams, gels, including products for tanning without sun and after sun care products).

The Cosmetics Standard requires that these products must:

- be a 'secondary sunscreen product' as defined in AS/NZS 2604:1998. As noted in relation to item 1, AS/NZS 2604:1998 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:

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- 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;
- 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.

Item 3 Skin care

This item of the Cosmetics Standard requires that antibacterial skin products:

- must only be presented as being active against bacteria;
- must not be presented as being:
 - active against viruses, fungi or other microbial organisms (other than bacteria);
 - for use in connection with disease, disorders or medical conditions:
 - active against a named bacterium that is known to be associated with a disease, disorder or medical condition;
 - for use in connection with piercing of the skin or mucous membrane whether for cosmetic or any other purpose;
 - for use in connection with any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids;
 - for use before any physical contact with any person who is accessing medical or health services, or who is undergoing any medical or health care procedure; and
 - for use in connection with any procedure involving venipuncture or delivery of an injection.

Item 4 Skin care

This item of the Cosmetics Standard requires that anti-acne products (including spot treatments, face scrubs, cleansers and masks) must be presented as controlling or preventing acne only through cleansing, moisturising, exfoliating and/or drying the skin.

Item 5 Oral hygiene

This item provides that where benefits are claimed to result from the use of products for care of the teeth and the mouth (such as dentifrices, mouth washes and breath fresheners), such benefits must be restricted to those consequential on improvements to oral hygiene, including for the prevention of tooth decay and/or the use of fluoride for the prevention of tooth decay. Further, the product must not claim benefits in relation to other diseases or ailments such as gum or other oral disease or periodontal condition.

Item 6 Hair Care

The Cosmetics Standard requires that anti-dandruff products must be presented as controlling or preventing dandruff only through cleansing, moisturising, exfoliating and/or drying the scalp.