Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

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NICNAS

Regulation of Cosmetic Chemicals: Final Report and Recommendations November 2005

An initiative of the NICNAS

Low Regulatory Concern Chemicals (LRCC) Reform Program

Industry, Government and Community working together

Regulating chemicals for your protection

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Regulation of Cosmetic Chemicals: Final Report and Recommendations

1 November 2005

In response to the Review of the Regulation of Products at the Cosmetic-Therapeutic Interface

An initiative of the NICNAS Low Regulatory Concern Chemicals (LRCC) Reform Program

Contents

Executive Summary

This is the Final Report and Recommendations for regulating cosmetic chemicals in Australia. Consistent with the Government's commitment for regulatory best practice, these recommendations have been developed following extensive consultation with Government, industry and the community.

Both the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Therapeutic Goods Administration (TGA) are of the view that these recommendations offer an enhancement to the regulation of cosmetics in general and more specifically will eliminate current confusion over how cosmetic products are defined. This is achieved through establishing a new system for better demarcation of what criteria define a chemical/product as a cosmetic, including presentation, claims and conditions of use applying to these products.

Key Outcomes:
The Government endorsed reforms can be broadly categorised into three areas, namely:

- **Innovative elements** to NICNAS
- **Modifications** to the existing NICNAS and TGA regulatory coverage
- **Consequential activities** primarily relating to implementation processes and practices to maintain confidence in the regulatory scheme.

These recommendations can be summarised in brief as follows:

1. INNOVATIVE ELEMENTS

A new ***NICNAS Cosmetic Guidelines*** that will:

consist of a set of cascading instruments which comprise:
(a) **Cosmetic criteria** for defining cosmetics;
(b) a **Table of cosmetic product categories**, including annotations to ensure compliance with performance or other standards as required; and
(c) A new mechanism for publicly identifying those chemicals that are **listed as prohibited or restricted cosmetic chemicals** for use in Australia.

The establishment of Cosmetic Criteria and Cosmetic Product Types within the proposed ***NICNAS Cosmetic Guidelines***, delivers greater clarity and certainty for industry, centralised regulation for cosmetics with NICNAS as a one-stop shop, and enhances consumer access to chemical safety information.

The establishment of a List of Prohibited or Restricted Cosmetic Chemicals will ensure greater compliance by industry and enhanced protection of consumers' health and safety.

2. MODIFICATIONS

The establishment of the ***NICNAS Cosmetic Guidelines***, it is now possible to effectively better regulate a number of products as cosmetics (currently regulated as medicines).

The products now **proposed to be regulated as cosmetics** (within the **conditions imposed** by the cosmetic guidelines) are:

- Antiperspirants
- Antidandruff shampoos (unscheduled)
- Sunscreens with SPF<4
- Moisturisers with secondary sunscreen
- Antibacterial skin washes
- Anti-acne skin cleansers

3. MAINTAINING CONFIDENCE IN THE REGULATORY PROCESSES

The ***NICNAS Cosmetic Guidelines*** will place the responsibility for cosmetics regulation solely with NICNAS. To ensure consumer and industry confidence that regulatory health, safety and environmental standards are maintained and/or enhanced, the ***NICNAS Cosmetic Guidelines*** will need*:*

(a) some form of legislative underpinning;
(b) an open and transparent consultative process to effect their development and implementation; and
(c) an open and transparent mechanism for maintaining the guidelines including establishment of any future precedent in decision making
⇒ an expert advisory group (the Cosmetic Advisory Group), with a membership drawn from relevant Government regulators, expert bodies, industry and the community, consistent with the NICNAS Community Engagement Charter is proposed.

Robust processes are needed to ensure that not only are appropriate controls in place for cosmetic products, but that there is an ability to effectively ensure compliance noting that up until now this has been a fundamental problem with determining cosmetic products by a therapeutic claims approach.

Introduction

In Australia, products commonly considered to be cosmetics are regulated by the Australian Government within the Health and Ageing portfolio, by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and certain cosmetics involving claims by the Therapeutic Goods Administration (TGA). While cosmetics are defined in the *Industrial Chemicals (Notification and Assessment) Act 1989*, the mechanism currently in place for distinguishing between products for regulatory purposes is that a product is deemed a cosmetic if it is not a therapeutic good (medicine). This reflects the historical timing of the establishment of the respective regulatory agencies, with NICNAS established after the TGA.

The cosmetics industry is global, characterised by companies marketing branded products across international boundaries. Australia accounts for about 1.2% of worldwide sales of cosmetic products, with many cosmetics imported as fully formulated and packed products. The industry is an extremely competitive one, with a high level of innovation, high product turnover and market driven style changes. The cosmetics industry, because of its competitive nature takes measures to ensure product safety above regulatory requirements. With global markets having expanded and the principle of regulatory harmonisation having been adopted by many governments, multinational companies aim to develop and sell new products around the world as quickly as possible and with minimal regulatory intervention.

Industry concerns regarding current regulatory framework

The Australian cosmetics industry argues that:

1. when products are defined as therapeutic goods in Australia, contrary to a cosmetic in some other countries, the TGA may require different data and sometimes additional assessment beyond that which would be required if the product were regulated as a cosmetic (ie a different regulatory burden); and
2. lack of cosmetic ingredients available for use in Australia compared to overseas chemical inventories prevents the timely introduction of safe and acceptable cosmetics (that are in use overseas) into Australia.

Background

NICNAS Low Regulatory Concern Chemicals reform

In announcing the Government response to the Chemicals and Plastics Action Agenda in November 2002, the Australian Government committed itself to, among other things, reducing unnecessary regulation while maintaining appropriate health, safety and environmental safety standards. In particular, the Government gave a commitment to continuing to work with industry to ensure the most efficient regulatory system is in place for industrial chemicals (including cosmetics), ie a system that does not inhibit the introduction of newer and safer chemicals. The Government agreed to consider and develop options for access to adequately assessed and/or tested chemicals presenting low regulatory concern.

The NICNAS Low Regulatory Concern Chemicals Task Force, made up of individuals from government, industry and the community, was established to investigate the reform of the regulation of industrial chemicals of low regulatory concern. The *Final Report and Recommendations for NICNAS Low Regulatory Concern Chemicals Reform Initiative* and the *Implementation Strategy for NICNAS Low Regulatory Concern Chemicals Reform Initiative* were published in June 2003 and July 2003, respectively.

Low Regulatory Concern Chemicals - Cosmetics

Acknowledging that cosmetics present regulatory challenges that are different to other industrial chemicals, cosmetics were considered separately under the LRCC. The LRCC Cosmetics Technical Working Group identified areas for reform for which consumer safety can still be maintained while reducing some elements of existing regulatory requirements. One such area was the regulation of products that currently lie at the regulatory interface between cosmetics and therapeutic goods (Recommendation 5.4).

Recommendation 5.4 of the LRCC Task Force Final Report:
"Recognising that negotiations are ongoing between industry and the Therapeutic Goods Administration (TGA), the LRCC Task Force recommends that the Parliamentary Secretary asks NICNAS and the TGA to examine the reform options for addressing the interface issues, in particular issues dealing with antiperspirants, mass market antidandruff shampoos, moisturisers with SPF, antibacterial skin washes and anti-acne cleansers."

Current regulatory approach

Up until now, it was regulatory practice for a product to be deemed a cosmetic if it was not a therapeutic good. This reflects the nature of the *Industrial Chemicals (Notification and Assessment) Act 1989* whereby NICNAS's coverage is defined by exclusion (ie not a sole therapeutic good, food or food additive, pesticide or veterinary medicine). NICNAS legislation is often described as a "catch-all" legislation aimed at avoiding regulatory duplication with other chemical regulatory sectors: food, medicines and pesticides/veterinary medicines.

Regulatory practice to date has seen "interface" products classified as therapeutic goods based on two factors.

(a) Claims made about the product – the key consideration for the classification of a product is its proposed claim(s). The *Cosmetic Claims Guidelines* prepared by the National Coordinating Committee on Therapeutic Goods (NCCTG) provides guidance on acceptable and unacceptable cosmetic claims.
(b) The composition of the product – although the composition of a product alone does not necessarily determine its classification, it is quite possible that an ingredient, or the concentration of an ingredient, may make the product unsuitable for classification as a cosmetic (through labelling requirements such as "poison").

While statutory definitions apply for cosmetics and therapeutic goods, some products share attributes of both cosmetics and medicines. To the consumer, the presentation of the goods, how they are described and advertised are most likely to be the major factors in making a decision. Regulators will also take into account the composition,

the intended use of the goods, any legislative provisions (especially definitions) and the precise label claims. There are, however, some products whose description as a medicine or a cosmetic is not easy, and a decision often involves some subjectivity.

Australian regulation vs international position

Table 1 summarises the international regulatory position for product types identified for reform through the Review.

Table 1:
Comparison of how products identified for reform are regulated in different countries

	Australia	Canada	New Zealand	United Kingdom/EU	United States
Antiperspirants	Therapeutic Good	Drug	Cosmetic	Cosmetic	Drug and Cosmetic
Antidandruff Shampoos (mass market)	Therapeutic Good	Drug	Related Product	Cosmetic	Drug and Cosmetic
Moisturisers with Sunscreen	Therapeutic Good	Drug	Cosmetic	Cosmetic	Drug and Cosmetic
Antibacterial Skin Washes	Therapeutic Good	Cosmetic (antibacterial cleanser). Drug (kills germs; antiseptic)	Cosmetic	Cosmetic	Cosmetic if no antibacterial claims. Drug if antibacterial claims are made
Medicated Skin Cleansers (for acne)	Therapeutic Good	Cosmetic (as a cleanser for acne-prone skin). Drug (treatment or control of acne)	Cosmetic	Cosmetic	Cosmetic (as a cleanser for acne-prone skin). Drug (treatment or control of acne)
Mouthwashes	Therapeutic Good or Cosmetic*	Drug or Cosmetic*	Related Product or Cosmetic depending on fluoride content	Cosmetic	Drug and Cosmetic*
Toothpastes (fluoride)	Therapeutic good or Cosmetic depending on fluoride content	Drug	Related Product	Cosmetic	Drug and Cosmetic

* Depends on the claims made for the product.

A key feature is that cosmetics are regulated differently around the world. The Australian industrial chemicals scheme, NICNAS, was specifically aligned with the European regulatory system when established, while the medicines regulatory scheme

was primarily aligned with North America. The current regulatory approach for defining cosmetics by their exclusion as medicines has created a disconnect with Australian industries with trading partners in the EU.

Objectives of Reform Activity

The principle objective of the reform is to determine best regulatory practice and to maintain and enhance the protection of public health, safety and environmental standards consistent with:

- relevant legislation;
- national approaches to ecologically sustainable chemicals management and regulation; and
- the Council of Australian Government (COAG) principles and guidelines.

Both industry and the Government support these objectives and have given it a high priority.

Consultant's Report and Consultation Processes

While the main trigger for the Review of the Regulation of Products at the Interface between Cosmetics and Therapeutic Goods **(**the Review) was Recommendation 5.4 of the NICNAS LRCC Task Force Final Report, it also addressed separate proposals from the Australian cosmetic industry to the TGA that certain products containing sunscreens should be regulated as cosmetics. The approach used for the reform process included an independent review of the policy framework for regulating products at the cosmetic-therapeutic interface (jointly commissioned by NICNAS and the TGA), extensive consultation, and development of options by the regulatory agencies based on these activities.

The NICNAS LRCC Cosmetics Working Group had identified product types that are currently regulated as medicines in Australia (with varying degrees of regulatory control) that they claim are perceived as cosmetics in the marketplace and hence were potential candidates for regulatory reform. Additional product types were identified through consultation during the Review.

The Review:

- considered the appropriateness of current legislation and guidelines in the regulation of products at the interface, including national and international frameworks and identified "grey areas" in current Australian regulatory frameworks;
- considered current systems for the regulation of the product types identified as candidates for review to determine whether they would be most appropriately regulated as medicines or cosmetics;

- proposed changes to improve regulation at the interface for identified product types, including changes that could enhance the transparency and useability of existing regulatory documents; and
- consulted extensively with interested parties and examined products on the market.

A draft Review Report was published in March 2005 for public comment.

Note: The draft Report also considered future implications for the regulation of medicines under the joint Trans-Tasman Agency (Joint Agency), however, given that the Joint Agency is yet to commence operations, it is considered that the reform proposals should only apply to the Australian regulation of therapeutic goods and cosmetics. Once the Joint Agency is established, any issues raised in this review relating to medicines can be discussed in terms of trans-Tasman arrangements. The cosmetic regulatory arrangements remain as an Australian only activity.

Table 2 summarises the Review recommendations developed by the consultant that were subject to extensive consultation so as to inform policy options in finalising the Review outcomes.

Table 2:
Summary of Review draft recommendations developed for public consultation

Cosmetics Claims Guidelines o should be established by the cosmetic and medicines regulators, in consultation with stakeholders and other relevant regulators o guidelines should be underpinned by legislation if necessary
Antiperspirants o preparations that derive their antiperspirant properties from inorganic salts (or their organic complexes) of aluminium, zinc or zirconium only should be reclassified as cosmetics o other preparations should be regulated as Class II medicines
Antidandruff preparations o antidandruff shampoos, hairdressings or lotions should be classified as therapeutic products o products not included in any Schedule to the SUSDP: (a) should be exempted from licensing; and (b) their manufacturing premises should be exempt from licensing

Sunscreens (Primary sunscreens where SPF is ≥ 4)

- should be classed as therapeutic products and described as Class I medicines
- SPF of each product must be determined in accordance with AS/NZS 2604:1998 (or acceptable international standard when one becomes available)
- all "mandatory" and "optional" performance statements and markings on the product label must be in accordance with AS/NZS 2604:1998 and no other

Sunscreens (Primary sunscreens where SPF is < 4)

- should not be classified as therapeutic products

Moisturisers that contain a sunscreen as and for a secondary purpose where the SPF ≥4

- should not be classified as therapeutic products provided that:
  - (a) they meet the definition of "secondary sunscreen product" as defined in AS/NZS 2604:1998; and
  - (b) any SPF or equivalent category description is disclosed on the label; and
  - (c) the SPF or equivalent category description disclosed on the label is determined by the method prescribed by AS/NZS 2604:1998 for the precise formulation; and
  - (d) the SPF as disclosed on the label does not exceed 20; and
  - (e) the formulation is not water-resistant; and
  - (f) there is an expiry date or use by date on the label if the product is not stable for at least 36 months; and
  - (g) no therapeutic claims, including any representation about skin cancer, are made; and
  - (h) any representation about anti-ageing can be made only if the product is defined as a "broad-spectrum product" within the meaning of AS/NZS 2604:1998; and
  - (i) the pack size does not exceed 300 mL or 300 g; and
  - (j) all performance statements and markings (both "mandatory" and "optional") are expressed on the product label in the manner prescribed by AS/NZS 2604:1998 and no other

Antibacterial skin washes (including antibacterial hand wipes)

- should be classified as therapeutic products (Class II medicines)
- The TGA, in conjunction with other regulators and in consultation with stakeholders and experts in public health and microbiology determine whether the routine domestic use of hand washes containing an antibacterial agent (irrespective of the stated purposes of the product):
  - (a) gives rise to the development of resistant strains of bacteria; and/or
  - (b) has a deleterious effect on micro-organisms that are harmless or whose presence has, in some way, a beneficial effect in humans
- If the decision is that there is no risk to public health from the routine domestic use of hand washes containing an antibacterial agent, further consideration should be given to the appropriate classification of these products across the therapeutic / cosmetic interface

Antibacterial skin cleansers (anti-acne products)

- that claim to prevent or treat acne or pimples should be classified as therapeutic products (Class II medicines)

Toothpastes and mouthwashes

- ***Desensitising toothpastes and gels*** should be classified as Class II medicines
- ***Toothpastes and gels that contain 1000 mg/kg or less of fluoride ion*** and that do not make therapeutic claims other than preventing caries or preventing or removing plaque should not be classified as therapeutic products
- ***Mouthwashes that contain an antibacterial substance*** for freshening the breath or for fighting plaque and where no therapeutic claims are made should not be classified as therapeutic products
- ***Mouthwashes that contain 220 mg/L or less of fluoride ion*** and that do not make any claim (except cosmetic claims) other then preventing caries or preventing or removing plaque should not be classified as therapeutic products

Personal lubricants

- should be classified as therapeutic products

Consultation

The review process operated in an open, consultative and transparent manner. The independent consultant, NICNAS and the TGA consulted widely with a broad range of stakeholders including: the cosmetics industry and its industry bodies; government and non-government organisations; and worker and community representatives.

Specifically, NICNAS and the TGA published an open letter to stakeholders outlining the process to be followed and seeking preliminary comment on the Review, in May 2004. The independent consultant undertook extensive consultation, including one-on-one interviews with interested parties in government, industry (including industry associations) and the community. The detailed draft discussion paper (including recommendations from the independent consultant) *Review of the Regulation of Products at the Interface between Cosmetics and Therapeutic Goo*ds was published on the NICNAS and TGA websites, in March 2005.

Consultations provided all interested parties an opportunity to:

- provide input into the review process, suggest reform proposals and engage in the reform process through the call for preliminary comment;
- identify strengths and weaknesses in proposals;
- comment on recommendations; and
- provide alternate solutions for reform proposals.

In addition, NICNAS and the TGA used their respective consultative mechanisms to obtain engagement of stakeholders. The NICNAS advisory groups consist of the NICNAS Industry Government Consultative Committee, the Community Engagement Forum and the NICNAS State/Territory Memorandum of Understanding Group. Similarly, the TGA sought the views of their stakeholders.

Summary of Public Submissions

Eighty-five written responses were received from a wide range of stakeholders including representatives of industry, consumers, regulators, medical practitioners and healthcare interest groups. To enhance transparency and make views known among all stakeholders, complete responses were published in full on the TGA and NICNAS web sites with the expressed consent of relevant parties. In general, industry groups commented on all reform proposals while health care professionals (including dermatologists and cancer councils) provided comment predominantly on the reforms proposed for products containing sunscreens.

It is clear through the consultations and comments received that the present regulatory arrangement for regulating products at the cosmetic-therapeutic interface is inadequate. There is an urgent need for clarity in the demarcation between cosmetic products and medicines. Industry and government organisations are supportive of progressing proposed reforms.

In general, the industry submissions were highly supportive of the reform options presented in the Review because of the perceived benefits they would bring to industry through a more efficient and effective regulatory system. There was overwhelming support for the reform process itself and the open and consultative manner in which the Review engaged industry, government and the community.

There was unanimous agreement to revising the *Cosmetic Claims Guidelines*. General agreement was noted for independent Review recommendations in relation to antiperspirants, primary sunscreens with SPF >4, primary sunscreens with SPF <4, toothpastes and mouthwashes.

The majority of the respondents disagreed with the Review recommendations to retain as medicines, anti-dandruff products, antibacterial skin washes, anti-acne products, desensitising toothpastes and gels and personal lubricants.

The Review recommendation that proved to be the most contentious was moisturisers with sunscreens for a secondary purpose. Comments were received from over 60 respondents including industry, consumers, practitioners, healthcare interest groups and government organisations. While a majority of industry groups argued for these products to be regulated as cosmetics, some industry groups disagreed and preferred to maintain the status quo as therapeutic goods. Some industry groups disagreed with the arbitrary cut-off of SPF 20 proposed by the Review. Most practitioner and healthcare groups advocated for their retention as therapeutic goods expressing concerns that if moisturisers with secondary sunscreens were treated as cosmetics,

there was the possibility of diminution of standards. They claim that if moisturisers are permitted to declare the SPF on the label there will not be a clear distinction between products that consumers rely on for prevention of sunburn and skin cancer versus those that are used for moisturising.

The cosmetic regulator confirms that the proposed reforms:

- do not raise issues in relation to their regulation as cosmetics;
- enhance product information to the consumer;
- improve OHS and environmental outcomes through assessment; and
- do not pose a risk from the lack of an efficacy assessment as products proposed for reclassification (noting some reclassification is subject to conditions) are low risk products and already regulated at a low level by the TGA.

Proposal for Reform – Findings and Recommendations

The Government has endorsed the reform of cosmetic regulation in Australia including the establishment of the new *NICNAS Cosmetic Guidelines.* This is in response to recommendations arising from the consultant's report, as well as the extensive comments received through the public comment phase.

This reform will provide mechanisms to better differentiate between the regulation of products as medicines or cosmetics. It is noted that the Review included comment on and recommendations that relate to the level of regulation of products as medicines, ie whether they were to be regulated as exempt, listable or registrable medicines. This matter is one for the Trans-Tasman regulation of medicines and as such is not addressed further.

The key feature of the Government's endorsed reform is the repositioning of the regulatory responsibility for defining cosmetics back to the cosmetic regulator, NICNAS. As such, a new approach is recommended to guide the regulatory interface between cosmetics and medicines.

The ***NICNAS Cosmetic Guidelines*** will effectively supersede the current NCCTG *Cosmetic Claims Guidelines*.

The ***NICNAS Cosmetic Guidelines*** will deliver:

- greater certainty for industry;
- greater consistency with existing legislative frameworks;
- enhanced transparency in defining what are cosmetics; and
- enhanced consumer access to chemical information on cosmetics.

The ***NICNAS Cosmetic Guidelines*** (draft at Attachment 1) will consist of a set of cascading instruments which comprise:

(a) **Cosmetic criteria** for defining cosmetics;
(b) a **Table of cosmetic product categories**, including annotations to ensure compliance with performance or other standards as required; and

(c) a new mechanism for publicly identifying those chemicals that are **listed as prohibited or restricted cosmetic chemicals** for use in Australia.

The development of the ***NICNAS Cosmetic Guidelines*** to replace the existing NCCTG *Cosmetic Claims Guidelines*, acknowledges that cosmetics are regulated by legislation, the *Industrial Chemicals (Notification and Assessment) Act 1989,* and places the responsibility for product classification more appropriately with NICNAS. This approach ensures that not only are appropriate controls in place for cosmetic products, but that there is ability to "police" compliance though legislative underpinning of these guidelines. This has up until now been a fundamental problem and has led to the default position of defining cosmetic products by therapeutic claim alone.

The ***NICNAS Cosmetic Guidelines*** will*:*

(a) need some form of legislative underpinning;
(b) be maintained by NICNAS; and
(c) be updated regularly on the advice of an expert advisory group (the Cosmetic Advisory Group), with a membership drawn from relevant Government regulators, expert bodies, industry and the community, consistent with the NICNAS Community Engagement Charter.

The draft Cosmetic Criteria (at Attachment 1) allow for the accommodation of changes in current regulatory approaches to antiperspirants, antidandruff shampoos, sunscreens with SPF <4, moisturisers with secondary sunscreens, anti-acne skin cleansers and antibacterial skin cleansers (see Table 3 below). The reform will mean that these products will be regulated as cosmetic products and not therapeutic goods, within specified conditions, as appropriate.

This shift in regulatory approach relies on cosmetic products being marketed and presented within defined parameters which are also legally enforceable to provide consumer confidence and assurances that any non-compliance can be adequately policed. This in particular addresses the concerns on the use of sunscreens in moisturisers.

It is vital that a clear distinction is made between primary sunscreens and the use of secondary sunscreens in moisturisers. Primary sunscreens form a vital component of Australia's public health policy on prevention of skin cancers and therefore, are required to meet the highest efficacy, safety and quality standards. This is achieved through their regulation as medicines and their central role in public health campaigns.

The Cosmetic Criteria specify strict conditions for the secondary use of sunscreens in moisturisers, so that they are marketed as cosmetics and more importantly are understood to be cosmetics by consumers (see Attachment 1). A further assurance that a minor use of sunscreens in cosmetics can be highly controlled, is that it will be subject to legislative underpinning including penalties for non-compliance.

Impact Analysis

This regulatory reform is subject to a Regulatory Impact Statement. Regulatory Impact Assessments (RIA) are available for each of the Review recommendations that require legislative and/or regulatory amendment.

The outcome of the RIA and the change in regulatory approach for cosmetics at the interface for the product types reviewed are summarised in Table 3. It is important to note that the key reform is in fact the development of the *NICNAS Cosmetic Guidelines* particularly the Cosmetic Criteria which provide the framework under which the regulatory changes identified as preferred options can operate. As such, the Cosmetic Criteria and other elements of the *NICNAS Cosmetic Guidelines* consist of a framework of principles and their finalisation will be undertaken by NICNAS with full stakeholder engagement.

Table 3:
Summary of recommendations for regulatory change for the product types reviewed

Product type	Current position	New approach
Antiperspirants	Therapeutic good – mainly Exempt	Reclassify as cosmetics
Antidandruff shampoos (unscheduled)	Therapeutic good – Exempt	Reclassify as cosmetics products that meet NICNAS Cosmetic Guidelines
Sunscreens, primary	Therapeutic good – Listed	Therapeutic goods
Sunscreens with SPF<4	Therapeutic good – Exempt	Reclassify as cosmetics
Moisturisers with secondary sunscreen	Therapeutic good – Listed (if SPF disclosed on label or therapeutic claims made) Cosmetic (if no SPF disclosed)	Reclassify as cosmetics products that meet NICNAS Cosmetic Guidelines
Sunscreens for lip use or as tinted facial make-up.	Cosmetic	Cosmetic
Antibacterial skin washes	Therapeutic good – Registered (if therapeutic claim is made) Cosmetic (if no claim is made)	Reclassify as cosmetics products that meet NICNAS Cosmetic Guidelines
Anti-acne skin cleansers	Therapeutic good – Registered (if therapeutic claim is made) Cosmetic (if no claim is made)	Reclassify as cosmetics products that meet NICNAS Cosmetic Guidelines

Product type	Current position	New approach
Mouthwashes	Therapeutic good – Registered (if therapeutic claim is made) Cosmetic (breath fresheners only)	Reclassify as cosmetics products that meet NICNAS Cosmetic Guidelines
Toothpastes, fluoride	Cosmetic	Cosmetic
Toothpastes, desensitising	Therapeutic good – Registered	Therapeutic goods
Personal lubricants	Therapeutic goods	Therapeutic goods

The Cosmetic market in Australia

The value of the Australian cosmetics and toiletries market has been estimated by local industry organisations at $5,200 million (retail), covering about 700 million units consumed annually. The hair care segment is the biggest, accounting for 24% of retail sales. Subsidiaries of foreign companies are the main suppliers. The major sources of imports are the United States (38%), France (19%), the United Kingdom (11%) and Germany (4%).

Product types identified for reform are currently subject to varying degrees of regulatory requirements by the TGA. The therapeutic goods scheme is a product registration scheme, where individual ingredients and products may require registration and assessment (dependent on type of goods). Proposals for reclassification as cosmetics apply mainly to products currently regulated as either exempt or listed medicines.

About the cosmetic regulator

NICNAS is a chemical entity based notification and risk assessment scheme (as opposed to the TGA that operates a product registration scheme), where all ingredients in a product require assessment if not already entered on the Australian Inventory of Chemical Substances (AICS) (unless subject to exemptions, when various compliance safeguards apply). Where products are reclassified as cosmetics, each individual ingredient not already listed on the AICS will require assessment or transfer onto the inventory through another acceptable mechanism.

Therefore, NICNAS and the TGA, in consultation with all industry stakeholders will establish an appropriate mechanism for the transfer of chemicals not listed on the AICS and currently included in products proposed for reclassification ensuring minimum impact on industry. Notwithstanding the potential impact, industry overwhelmingly supports reclassification of these product types as cosmetics as evidenced by written submissions through the public call for comment.

The affected parties will be industry, Government, consumer/community, workers and the environment (by indirect means).

Benefits

The expected benefits are, for:

- Government – enhanced clarity of regulatory roles and responsibilities of NICNAS and the TGA with respect to cosmetic chemicals, regulatory efficiency through use of resources and regulatory effort on areas of higher risk;
- Community – improved access to information on the composition of consumer products through full ingredient disclosure on cosmetic product labels, introduction of a mechanism to ensure chemicals not permitted for use in cosmetics are clearly identifiable;
- Workers – safer chemical use through occupational health and safety assessments for all new cosmetic chemicals and chemicals of concern manufactured and formulated in Australian workplaces;
- Industry – more consistent approach to regulatory requirements, lower compliance costs with a one-stop shop for cosmetics regulation, harmonisation with international cosmetics regulation will reduce trade barriers, introduction of a mechanism to ensure chemicals not permitted for use in cosmetics are clearly identified;
- Small business – addresses concerns regarding over-regulation of certain cosmetics, harmonisation with international cosmetics regulation will reduce trade barriers; and
- All sectors – overall better access to information on cosmetics through ingredient labelling and publication of prohibited/restricted chemicals lists, enhanced health and environmental outcomes.

Regulatory Best Practice

The affected parties, ie Government, industry and the community were involved from the outset and are expected to play a significant role in the implementation phase. The reform options have been designed to minimise the compliance burden on industry while maintaining and enhancing human health, safety and environmental standards. The proposed reforms will align Australian regulation of certain products with international regulatory standards and therefore minimise trade barriers.

The reform addresses what has become a disconnect in the regulatory framework whereby the cosmetics regulator relied on the therapeutic goods regulator to determine what was a cosmetic. This reflects practices of the past rather than a considered implementation of regulatory policy. The move to the new *NICNAS Cosmetic Guidelines* is considered to be an enhancement to the regulatory framework providing clarity and transparency for industry, Government and consumers, as well as enhancing environmental and occupational health and safety aspects of cosmetic safety and improving consumer access to chemical information.

Implementation

The Government has endorsed the reform of cosmetic regulation in Australia including the establishment of the new *NICNAS Cosmetic Guidelines.*

To implement these reforms, NICNAS will:

- work in partnership with community, industry and Government consistent with its Community Engagement Charter
- Establish an Implementation Working Group with a view to:
    - Reviewing and finalising the *NICNAS Cosmetic Guidelines;*
    - Establishing a group of experts to provide ongoing advice to the Director, NICNAS on matters relating to the *NICNAS Cosmetic Guidelines*; and
    - Determining a mechanism for transfer of cosmetic chemicals from the Australian Register of Therapeutic Goods (ARTG) to Australian Inventory of Chemical Substances (AICS), where needed.

NICNAS will also identify the appropriate legislative tool(s) for implementation of these reforms.

Attachment 1

Note:
These are draft guidelines. They will be finalised by an Implementation Working Group comprised of community, industry and relevant Government agencies.

PROPOSED NEW
NICNAS COSMETIC GUIDELINES
DRAFT

This document is a regulatory guideline issued by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

The definition of a cosmetic under the *Industrial Chemicals (Notification and Assessment) Act 1989* is consistent with that in the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991, ie "A substance or preparation intended for placement in contact with any external part of the human body, including: the mucous membranes of the oral cavity; the teeth; with a view to: altering the odours of the body; or changing its appearance; or cleansing it; or maintaining it in good condition; or perfuming it; or protecting it."

These *Cosmetic Guidelines* consist of:

1. **COSMETIC CRITERIA** that define what products are considered as cosmetics in Australia;
2. **TABLE OF COSMETIC PRODUCT CATEGORIES** generally considered as cosmetics in Australia; and
3. **LIST OF PROHIBITED OR RESTRICTED COSMETIC CHEMICALS IN AUSTRALIA**.

NICNAS will maintain the *Cosmetic Guideline*s through its established practices outlined in the NICNAS Community Engagement Charter and proposes to establish a Cosmetic Advisory Group with a membership drawn from relevant Government regulators, expert bodies, industry and the community.

1. COSMETIC CRITERIA

Products are determined to be cosmetics and not therapeutic goods based on the following criteria [note: *all criteria need to be satisfied for classification as a cosmetic*]:

- the proposed use of the product and its consistency with the definition of cosmetic in Australia (*Industrial Chemicals (Notification and Assessment) Act 1989* and *Trade Practices (Consumer Product Information Standards)(Cosmetics) Regulations 1991*):

        - meaning a substance or preparation intended for placement in contact with any external part of the human body, including the mucous membrane of the oral cavity, and the teeth (ie general topical uses), AND
        - used for altering the odour, changing appearance, cleansing, maintaining in good condition (including moisturising and controlling), perfuming or protecting the consumer;
        - but NOT for prevention, diagnosis, treatment or cure (which is a therapeutic use); AND
    - does not contain a scheduled medicinal substance (ie not included in S2, S3 or S4 or S8 of the SUSDP) AND
    - the context in which the product is marketed (at a particular point in time taking into account the look, the packaging, advertising and /or the label statements
        - including the full ingredient disclosure for cosmetic products where the ingredients of are to be listed on the product label in descending order calculated by either mass or volume.); and
        - labeled and presented as being explicitly for cosmetic purposes only; and/or
        - the product name of itself would NOT make the product a therapeutic good unless that name makes a reference to a disease, condition, ailment or defect of the human body; AND
    - meets all stipulated conditions detailed in the **TABLE OF COSMETIC PRODUCT CATEGORIES** AND
    - is **NOT** prohibited for use or meets restrictions for use in cosmetics (see the **LIST OF PROHIBITED OR RESTRICTED COSMETIC CHEMICALS)**.

2. TABLE OF COSMETIC PRODUCT CATEGORIES

The following Table outlines product categories and their uses that are considered as being cosmetics in Australia. This List is not exhaustive and industry should advise NICNAS if they wish to seek amendment to the Table. Product categories and types are based on the EU Cosmetics Directive (1976/768/EEC) Annex I.

Product category	Product types
Face and Nail	Products for nail care Products for colouring nails/varnish Tinted bases/foundation (liquids, pastes, powders) o with or without SPF o (a) they meet the definition of "secondary sunscreen product" as defined in AS/NZS 2604:1998; and (b) any SPF or equivalent category description is disclosed on the label; (c) the SPF or equivalent category description disclosed on the label is determined by the method prescribed by AS/NZS 2604:1998 for the precise formulation.

Product category	Product types
Face and Nail (*continued*)	Products for making-up and removing make-up from the face and eyes. Products intended for application to the lips o with or without SPF o (a) they meet the definition of "secondary sunscreen product" as defined in AS/NZS 2604:1998; and (b) any SPF or equivalent category description is disclosed on the label; and (c) the SPF or equivalent category description disclosed on the label is determined by the method prescribed by AS/NZS 2604:1998 for the precise formulation. Face masks (excluding peeling products)
Hair care	Hair tints and dyes and bleaches Products for waving, straightening, and fixing Setting products Cleansing products o Lotions o Powders o Shampoos o Antidandruff shampoo (control through cleansing, moisturising and/or exfoliating the scalp) Conditioning products (lotions, creams, oils)
Oral Hygiene	Products for care of the teeth and the mouth including: o Dentifrices eg. toothpastes/gels (excluding desensitising toothpastes/gels) o Mouthwash o Dental bleaches/whiteners Breath fresheners
Perfumes	Perfumes Toilet waters Eau de Colognes
Personal Hygiene	Deodorants Antiperspirants Cleansers eg o Toilet soap o Deodorant soap o Astringent o Skin washes

Product category	Product types
Personal Hygiene (*continued*)	Antibacterial skin washes o excluding products used for: (a) prevention of the transmission of disease (b) specifically for use in clinical/surgical settings (c) specifically for food handing Anti-acne products (control through cleansing, moisturising and/or exfoliating the skin) Shaving products (creams, foams, lotions) Bath and shower preparations (salts, foams, oils, gels, etc.) Depilatories
Skin Care	Moisturising products for dermal application eg creams, lotions, gels, foams (without SPF) Moisturising products for dermal application eg creams, lotions. gels. foams (with SPF) o Moisturisers that contain a sunscreen as and for a ***SECONDARY PURPOSE***** where the ***SPF ≥4*** and does not exceed **15** provided: (a) they meet the definition of "secondary sunscreen product" as defined in AS/NZS 2604:1998; and (b) Any SPF or equivalent category description is disclosed on the label; and (c) the SPF or equivalent category description disclosed on the label is determined by the method prescribed by AS/NZS 2604:1998 for the precise formulation; and (d) the formulation is not water-resistant; and (e) there is an expiry date or use by date on the label if the product is not stable for at least 36 months; and (f) no therapeutic claims, including any representation about skin cancer, are made; and (g) any representation about anti-ageing can be made only if the product is defined as a "broad-spectrum product" within the meaning of AS/NZS 2604:1998; and (h) the pack size does not exceed 300 mL or 300 g; and (i) all performance statements and markings (both "mandatory" and "optional") are expressed on the product label in the manner prescribed by AS/NZS 2604:1998 and no other; and (j) labelling, marketing and packaging clearly indicates the product is for use as a cosmetic. [** Note: (a) a level of SPF 15 is set based on the AS/NZ 2604:1998 that specifies products claiming SPF>15 as being very high performance sunscreen which in a public health context is generally deemed to be a primary sunscreen

Product category	Product types
Skin Care (*continued*)	(b) due to the high public health importance that primary sunscreens play in protecting Australians from the harmful effects of the sun, cosmetic can only contain SPF as secondary purpose and must not be substituted for primary sunscreen purposes, hence there are strict conditions applying to the use of secondary sunscreen in moisturisers. A breach of any of these conditions will be subject to penalties under the *ICNA Act 1989*] Emollients eg creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc) Sunbathing products (without SPF) Products for tanning without sun Skin-whitening products Anti-wrinkle products After-bath powders Hygienic powders

3. LIST OF PROHIBITED OR RESTRICTED COSMETIC CHEMICALS IN AUSTRALIA*

The List is based on existing controls/bans for cosmetic ingredients such as restrictions/bans in Appendix C of the SUSDP or a recommendation arising from a NICNAS assessment.

Chemical Name	Prohibition or Restriction	Reference
Phenylenediamines	Prohibited in preparation for skin colouration (eg tattoos)	Appendix C SUSDP
Diethylphthalate	Restriction: in sunscreens except at 0.5% or less	Appendix C SUSDP
Dimethylphthalate	Restriction: in sunscreens except at 0.5% or less	Appendix C SUSDP
coal tar	Prohibition	Appendix C SUSDP

[Note: This list would be developed further by the proposed Cosmetic Advisory Group using NICNAS AICS annotations/restrictions, the NICNAS assessment reports, the SUSDP and consideration of other international "negative" lists- eg US FDA and EU Cosmetic Directive.]

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