

REGULATION IMPACT STATEMENT

Review of Trade Practices (Consumer Product Information Standards) (Cosmetics)
Regulations 1991
(Cosmetic Regulations)

FEBRUARY 2008

Product Safety Compliance Section
Australian Competition and Consumer Commission

Introduction

Background

The Australian Competition and Consumer Commission (ACCC) has the responsibility for administering the mandatory *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991* (Cosmetic Regulations) pursuant to the *Trade Practices Act 1974* (the Act).

The Cosmetic Regulations were originally gazetted on 29 October 1991 and amended in December 1998 by the *Trade Practices (Consumer Product Information Standards) (Cosmetics) Amendment Regulations 1998 (No.1)*. This amendment was made to address changes in the marketplace.

The 1998 amendments amongst other things allowed the use of International Nomenclature Cosmetic Ingredient names. All suppliers – including manufacturers, importers, distributors and retailers – must comply with the mandatory information standard, which is enforced by the ACCC. Non-compliance with the mandatory information standard is an offence under the Act and may result in fines, recalls or other countermeasures being imposed on suppliers.

The Cosmetic Regulations apply to cosmetic and toiletry products manufactured in or imported into Australia after 31 October 1993. The Cosmetic Regulations set out requirements about how information about ingredients is displayed on the label of the cosmetic product. The Cosmetic Regulations do not regulate the actual content of cosmetics products or contain any other requirements in relation to cosmetic products.

The purpose of the Cosmetic Regulations is to address a previous market failure whereby consumers did not have sufficient information about cosmetic ingredients to avoid, and/or obtain treatment for, adverse reactions caused by some cosmetics. The Cosmetic Regulations:

- enable consumers to identify those products containing ingredients which may irritate them or cause an allergic reaction;
- enable consumers to identify products which contain ingredients which are found to be potentially harmful after the product has been manufactured;
- enable health care providers to recommend appropriate treatment;
- reduce the cost to governments of medical and pharmaceutical benefits which arise when consumers seek treatment for allergic reactions to cosmetics;
- satisfy consumer needs for ingredient information about cosmetic products, especially at retail outlets, such as supermarkets, where information cannot be obtained from sales assistants; and
- enable consumers to make value comparisons between similar products.¹

¹ Department of Treasury, Consumer Affairs Division, *Regulation Impact Statement – Trade Practices (Consumer Product Information Standards) (Cosmetics) Amendment Regulations 1998*, June 1998

Scope of Regulations

The Cosmetic Regulations were developed as a product information standard under S65D of the Act. Section 65D provides that regulations may, in respect of goods of a particular kind, prescribe a consumer product information standard consisting of such requirements as to:

- a) the disclosure of information relating to the performance, composition, contents, methods of manufacture or processing, design, construction, finish or packaging of the goods; and
- b) the form and manner in which that information is to be disclosed on or with the goods;

as are reasonably necessary to give persons using the goods information as to the quantity, quality, nature or value of the goods.

The Cosmetic Regulations define “cosmetic product” as 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 and 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.

While it is ultimately the role of the Courts to interpret regulation the ACCC can provide guidance on regulations it administers and it interprets cosmetic products to include, but not be limited to, the following:

- creams, emulsions, lotions, gels or oils for the skin;
- face masks;
- tinted bases including liquids, powders or pastes;
- make-up, after-bath or hygiene powders;
- toilet or deodorant soaps;
- perfumes, toilet waters or eau de colognes;
- bath or shower preparations including salts, foams, gels or oils;
- depilatories;
- deodorants;
- hand cleansers;
- hand protective creams or barrier creams;
- hair products including hair tints or bleaches, products for waving, straightening or fixing, setting products including lotions, creams or oils, conditioning products including lotions, creams or oils, hairdressing products including lotions and lacquers, brilliantines, hair tonic and shampoos;
- products for make-up and removing make-up from the face or eyes;
- products intended for application to the lips;
- products for the care of the mouth or teeth;
- products for nail care or make-up;
- shaving creams, foams, lotions or soaps;
- products for tanning without the sun;
- skin whitening products;
- temporary tattoos;
- fake nails and the adhesive for fake nails.

The Cosmetic Regulations require cosmetic products to be fully labelled with their ingredients, as follows:

- The ingredients must be specifically identified and listed in descending order calculated by either mass or volume. The quantity or percentage of each ingredient does not need to be declared.
- Alternatively, ingredients may be listed in the following way:
 - all ingredients (except colour additives) present in concentrations greater than 1% shall be listed in descending order by mass or volume;
 - followed by ingredients (except colour additives) present in concentrations of less than 1% in any order; and
 - followed by colour additives, listed in any order.

Incidental ingredients do not need to be disclosed. They are ingredients which have no technical or functional effect in the cosmetic product and are present in a cosmetic at insignificant levels. (In many cases the manufacturer or importer would not be aware of all the trace materials in each raw material used in a formulation, and would thus be unable to disclose them.)

Fragrances and flavours are the only ingredients which may be generically identified as either “fragrance” or “flavour” although the manufacturer may specifically identify the ingredients of the fragrances or flavours if desired.

All ingredients must be included in the one list. The names of the ingredients in the list must be either their English names or their International Nomenclature Cosmetic Ingredient (INCI) names. There may also be a list of ingredients in another language.

The list of ingredients must be prominently shown, clearly visible and legible.

The standard requires that cosmetic products be labelled with a list of all ingredients on the container or, if not packed in a container, on the product itself. The Cosmetic Regulations allow suppliers to provide the list of ingredients in other ways if the size, shape or nature of a cosmetic product or its container prevents the list of ingredients being declared on the container or on the product.

Other ways to provide information to the consumer could include the use of leaflets, pamphlets, brochures, labels, manuals, swing tags, display panels, posters or similar methods which are attached to, or provided with, or are prominently displayed alongside cosmetic products.

The Cosmetic Regulations provides for the Minister responsible for consumer affairs to grant an exemption or trade secret status to an ingredient. The Cosmetic Regulations do not apply to therapeutic goods² or free samples or testers of cosmetic products.

² Within the meaning of the *Therapeutic Goods Act 1989*

Nature of the market

A significant part of the cosmetics industry is global, characterised by companies marketing branded products across international boundaries. There are few barriers to local entry and local suppliers range from cottage industries to multinational companies. A 2005 Department of Health report³ notes that Australia accounts for about 1.2% of worldwide sales of cosmetics products, with many cosmetics imported as fully formulated and packaged products. The European market for cosmetic products is estimated to be worth approximately 65 billion Euro.⁴

At the time of the 1991 review of the Cosmetic Regulations, cosmetic products were imported into Australia from over 50 countries.⁵ The ABS 2004-05 Manufacturing Industry Report (8221.0) shows that income from Australian cosmetic, toiletry and pharmaceutical product preparation including manufacturing, sales and service amounted to \$645 million in 2004-05. Industry value added amounted to \$191 million for the same period.

The ABS February 2007 Retail Trade report (8501.0) stated that Australian pharmaceutical, cosmetic and toiletry retailing amounted to \$721.9 million in January 2007 and \$697.6 million in February 2007. It should be noted that figures for pharmaceuticals which fall outside the scope of the Cosmetics Regulations are included in these figures.

Based on value the USA, France, UK, Italy, China and Germany had the highest import volume sales across the 4 months November 2006, December 2006 and January and February 2007.

Rationale for review

Mandatory regulations should be regularly reviewed to ensure that they remain relevant and continue to address the problems that resulted in the need for regulatory intervention, and to ensure that new developments are appropriately integrated into the regulations.

The Office of Best Practice Review's new draft Guidelines provide that regulation be reviewed on a frequent basis. The Cosmetics Regulations were last reviewed in 1998. An industry association has also made a request for amendments to the Cosmetic Regulations.

³ Department of Health and Ageing Therapeutic Good Administration, *Regulation of Cosmetic Chemicals: Final Report and Recommendations November 2005*, 1 November 2005,

⁴ EU Press Release, *Commission moves on with simplification programme in the field of cosmetics*, Brussels, 12 January 2007 – IP/07/37

⁵ Explanatory Statement, Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 No.327. Accessed 24/4/07 < <http://www.timebase.com.au/MALTweb/?product=TP>>

Scope of the Review

The review has:

- ascertained if there is a justifiable need for ongoing government intervention in maintaining mandatory labelling requirements for cosmetics supplied in Australia;
- ascertained if the particulars of the Cosmetics Regulations continue to be relevant;
- considered submissions from a key industry association, for a number of amendments to be made to the Cosmetic Regulations; and
- considered submissions from other key stakeholders.

The industry association's request has been considered in a wider context of issues relating to enforceability of the regulations, parity with international standards and new technologies (internet cosmetic sales).

The industry association views amendments as necessary in order to bring the Cosmetic Regulations in line with international standards and practices with regard to cosmetic labelling, especially with regard to the terminology or nomenclature used.

Interaction with other domestic regulation

In Australia, individual ingredients of products including cosmetics are assessed by the Department of Health and Ageing *National Industrial Chemicals Notification and Assessment Scheme* (NICNAS). In addition, where there is therapeutic effect products including some cosmetics are assessed and regulated by the Therapeutic Goods Administration (TGA). The ACCC Cosmetics Regulations generally apply to cosmetics products without a therapeutic effect and therefore not subject to TGA regulation.

The TGA assessments place emphases on human toxicology, whereas NICNAS assessments also take environmental and occupational health and safety issues into account. NICNAS administers the *Industrial Chemicals (Notification and Assessment) Act 1989* which establishes a system of notification and assessment of industrial chemicals to protect health and safety and the environment and to provide for the registration of certain persons proposing to introduce industrial chemicals.

There has been some confusion about how cosmetic products are defined resulting in some regulatory overlap between the TGA and the Trade Practices Cosmetic Regulations. Cosmetic Reforms initiated in November 2005 establish a system for better demarcation of what criteria will define a product as a cosmetic. Amendments to the *Industrial Chemicals (Notification and Assessment) Act (Cosmetics) 1989* (ICNA Act) which came into effect on 17 September 2007 incorporate the regulation of cosmetics into the current regulatory scheme for industrial chemicals. The amendments extend the ability of NICNAS to regulate Cosmetics by enabling the Minister to make national standards for cosmetic products, with possible implications for the ACCC's future role in regulating Cosmetics. NICNAS have amended the ICNA Act so that some products which were previously regulated as therapeutics by

the TGA will now be classified as cosmetics and will need to be labelled according to our *Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991*.

As of 17 September 2007, the following products will now be considered to be cosmetics:

- anti-acne products;
- antibacterial skin products;
- antidandruff products;
- antiperspirants;
- moisturisers with secondary sunscreen SPF 4-15 inclusive; and
- sunscreen products SPF <4.

Unless there is change made by the TGA there will continue to be some circumstances where some of these product categories above will still be considered therapeutics. For example, under the definition of therapeutic goods in the Therapeutic Goods Act 1989, anti perspirant continues to meet the definition of therapeutic but it is an exempt therapeutic good pursuant to the Therapeutic Goods Act 1989, Schedule 5, Item 8 (b). This makes the product exempt from having to be registered on the Australian Register of Therapeutic Goods (ARTG) and from being manufactured under good manufacturing practice (GMP). However the product would still have to accord with the TGA labelling order. Note the TGA labelling order does not require a full ingredient list.

Under the ICNA Act, the Health Minister has introduced a National Cosmetic Standard to deal with some of the product categories above, which are now termed cosmetic products. Out of the products listed above the following products have additional conditions applied to them under the NICNAS Cosmetic Standard:

- tinted bases or foundation (liquids, pastes or powders) with sunscreen;
- products intended for application to the lips with sunscreen;
- moisturising products with sunscreen for dermal application, including anti-wrinkle, anti-ageing and skin whitening products;
- sunbathing products with a sun protection factor of at least 4 and not more than 15;
- antibacterial skin products;
- anti acne products (including spot treatments, cleansers, face scrubs and masks);
- products for the care of the teeth and the mouth (eg dentifrices, mouth washes and breath fresheners); and
- anti-dandruff products.

The conditions for these products are specified in the NICNAS Cosmetic Standard and explained in the NICNAS Cosmetic guidelines.

The *Customs (Prohibited Imports) Regulations 1956*, schedule 4 prohibits ingredients that are prohibited from importation due to safety and health or other reasons.

The *Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)* disallows some substances or substances over a certain quantity which may be classified as drugs (therapeutics) or poisons from being present in cosmetic formulations and may require certain cautionary or warning language to be added to the label for protection of the consumer, if there is a specific ingredient in the cosmetic product.

Comparison with overseas regulatory requirements

As part of the review, a comparison of key international standards was undertaken. If the Australian Cosmetic Regulations were markedly different from other markets around the world then importers may be reluctant to supply the Australian market because of cost considerations. However research into the EU, UK and Canadian Regulatory systems reveal that their requirements are in fact similar to the Australian requirements in that they require a detailed ingredient list for cosmetics (unless an exemption applies). However there are some differences in these standards and how they are applied.

In Australia, US and the EU, cosmetics must have a list of ingredients regardless of whether it is hazardous or not. In NZ, suppliers currently appear to have a number of choices in terms of labelling; one choice is that a supplier may list only the hazardous substances so that in some cases if there are no hazardous substances, no ingredient disclosure would be required. However as most cosmetics are imported into NZ, the NZ authorities assume that most cosmetics will have ingredient labelling (regardless of hazardous substances) because it will be labelled for the EU and US markets. However it is possible under this regime that some cosmetics imported into New Zealand may currently have no ingredient labelling at all.

In NZ the Cosmetic Group Standard was introduced in July 2006 however the transitional provisions do not expire until 1 July 2008. Hence the general requirements for labelling set out in Schedule 1, Clause 2 (2) (a) and (b)⁶ do not come into force until 30 June 2008⁷. It is noted that some limited cosmetic regulation existed prior to the Cosmetic Group Standard in the NZ Medicines Act and Regulations 1981.

The Environmental Risk Management Authority (ERMA) in NZ are currently conducting a review to resolve some issues which have arisen since the Cosmetic Group Standard was introduced. Some of those issues include inconsistency in Schedule 1, between clause 2 (2) (b) and 2 (4). Schedule 1, clauses 2 (2) (a) and (b) provide a number of options for compliance whilst clause 2(4) appears to require compliance with the current EU Directive relating to conditions for labelling. The NZ Cosmetic Group Standard adopts annexes out of the EU Directive but not the wording from Article 6 of the EU Directive which specifies that a full ingredient list is required.

⁶ Cosmetics Products Group Standard, Schedule 1, Clause 2 (2) The labelling on a substance must comply with one of the following:

(a) the labelling provisions of the Hazardous Substances (Identification) Regulations 2001, the Hazardous Substances (Emergency Management) Regulations 2001 and the Hazardous Substances (Disposal) Regulations 2001; OR (b) the current labelling requirements for cosmetic products of Australia, USA or the European Union, as if the substance were for sale or supply in those countries.

⁷ Compliance with Information Requirements which includes labelling requirements in Schedule 1 are not in force till 30 June 2008

The Schedules that adopt the EU annexure conditions, do not explicitly set out that a full ingredient list is required hence there has been some confusion regarding the requirements of the NZ Cosmetic Group Standard. Another issue has been that there are some differences in the requirements between the EU and US labelling requirements, for example colour specifications – chemical index numbers are different in the EU as compared to the US.

As the labelling requirements (of the NZ Cosmetic Group Standard) have not come into force, suppliers can still use the old system whereby there is no labelling requirements (apart from the Medicine Act which provides for a definition of cosmetics 2(1) and 63(1) describes enforcement powers and the NZ Medicines Regulations relate to the manufacturing of cosmetic products). Once the new labelling requirements come into force in June 2008 suppliers, (as the NZ Cosmetics Standard currently stands) will have the choice to adopt the labelling requirements of the EU, US, Australia or label hazardous substances over certain thresholds only.

The NZ Cosmetic Group Standard appears to have adopted the EU requirement for listing fragrance, that requires the supplier to specify if the fragrance contains any of the 26 known human allergens. While the NZ Cosmetic Group Standard has adopted the list of substances setting out the human allergens to be listed in Schedule 5 from number 67 to 92 in the Schedule 5 (which is identical to the 26 allergens listed in Article 6(1) (g) of the EU Directive), the NZ Cosmetic Group Standard has not directly adopted Article 6 of the EU Directive. It is understood that the ERMA is working to resolve any inconsistencies in the NZ Cosmetic Group Standard.

The European Commission commenced a review of the Council Directive 76/768/EEC of 27 July 1976 with the aim of simplification. In the last 30 years the Directive has been amended 48 times. According to the European Commission this has rendered many provisions unclear. The European Commission has also noted that detailed regulation of individual substances used for cosmetics has proven complex, resource intensive and difficult to administer.⁸

The EU is looking to remove the Cosmetic Directive and implement a Cosmetic Regulation which will be automatically adopted by the 27 countries of the EU.

In NZ, one option under new (yet to be introduced) labelling requirements of the Cosmetic Group Standard; is to limit labelling to any substance imported or manufactured for use as a cosmetic product, where that cosmetic product classifies as hazardous according to the hazard classification set out in the *Hazardous Substances (Classification) Regulations 2001*.⁹ The NZ Regulation focuses on hazardous substances as opposed to ingredients which may cause allergic reaction. In this way the NZ regulation may be viewed as different to current regulation in Australia and the EU.

The EU Directive sets out a list of substances which cannot be included in the composition of cosmetic products (Annex II) and a list of substances which cosmetic

⁸ EU Press Release, *Commission moves on with simplification programme in the field of cosmetics*, Brussels, 12 January 2007 – IP/07/37

⁹ *Hazardous Substances (Classification) Regulations 2001* Section 4(1)

products may not contain, outside the restrictions and conditions laid down (Annex III). The EU Directive also contains lists of colourings (Annex IV), preservatives (Annex VI) and UV filters (Annex VII) permitted in cosmetic products.¹⁰ The EU label has to contain a list of ingredients, in descending order, preceded by the word 'ingredients'. Perfume and aromatic compositions shall simply be referred to by the words 'perfume' or 'aroma', except where these have been identified as an important cause of contact-allergy reactions in fragrance-sensitive consumers.¹¹

The European Commission has submitted a proposal to the EU Parliament to streamline the Cosmetic Directive into one single regulation for all 27 EU nations. The main change focuses on a shift from Directives to one single piece of legislation with the focus on 'in market' rather than 'pre market' control. A Directive requires member states to implement the changes, whereas one single regulation would be applicable to all nations automatically. The EU is also looking at ways to have an electronic system to provide for the regular notification of changes to INCI dictionary.

The proposed changes are to be considered by the European Parliament in April 2009 and are expected to be adopted in June 2009 and are likely to be implemented throughout Europe eighteen months later.¹²

Product related hazard – health risks of cosmetics

In Australia cosmetic products are marketed to both adults and children. Children's products that are likely to fall within the reach of the Cosmetics Regulations include temporary tattoos, lipsticks, face paints and fake nails.

Most cosmetics do not appear to pose a health risk when the directions on the label are followed and when the product is used properly. However some of the ingredients in cosmetics can cause allergic reactions and other adverse effects to certain individuals.

According to Health Canada¹³ an estimated 2 to 5 per cent of adults may experience mild reactions to the chemicals in cosmetics. The most common reaction is a skin rash. When this happens, most individuals simply stop using the product and the condition clears up on its own. However, a small percentage of individuals have more serious reactions that may result in a reduced quality of life, loss of income or school-time, increased health risks and increased demands on the health system. Examples of such adverse reactions to cosmetics include painful eye irritations, swelling of the face, and hair loss. In rare instances, individuals with a severe allergy to an ingredient may develop breathing problems. Also, some cosmetics may be toxic to children if swallowed.¹⁴

The main cause of injury which has been brought to the ACCC's attention in terms of injury associated with cosmetics in both the area of adult and child cosmetics arises from the potential of certain ingredients to cause an allergic reaction.

¹⁰Europa website - <http://www.europa.eu/scadplus/leg/en/lvb/l21191.htm>

¹¹Europa website - <http://www.europa.eu/scadplus/leg/en/lvb/l21191.htm>

¹²Speech by Bertil Heerick, Director General – Colipa, 26 October 2007

¹³Health Canada website, accessed May 2007 <http://www.hc.sc.gc.ca/iyh-vsv/prod/cosmet_prod_e.html>

¹⁴Health Canada website <http://www.hc-sc.gc.ca/iyh-vsv/prod/cosmet_prod_e.html>

The problem to be addressed

There is an ongoing requirement to address a previous market failure whereby consumers did not have all the necessary information about cosmetic ingredients. Before the Cosmetic Regulations were introduced dermatologists treating allergic reactions previously had to obtain information on cosmetic ingredients from manufacturers, which delayed identification of allergens and treatment of allergic reaction. This resulted in increased cost to governments, as a result of claims on health care and pharmaceutical benefit schemes and increased costs to consumers in terms of pain and suffering and medical costs.

The basis for the ACCC review of the Cosmetic Regulations is to ascertain whether regulation continues to be an appropriate vehicle to address the need for consumers to be provided with information on cosmetic ingredients in order to reduce the potential risk of injury.

The review has also considered whether the Cosmetic Regulation is line with international standards so as to not result in unnecessary technical barriers to trade as per Australia's World Trade Organisation¹⁵ agreement. It is also noted that under the terms of the Agreement on Technical Barriers to Trade, a Government is able to regulate to protect human life and health, especially where it can be shown to be necessary to achieve reasonable levels of consumer protection.

In light of developments in the regulation of cosmetics domestically and internationally, as well as industry requests for change, the ACCC has re-examined the Cosmetic Regulations to ascertain if the Cosmetic Regulations in their current form adequately address the need for labelling of cosmetic products, and what changes, if any, could be made to maintain the relevancy and efficacy of the Cosmetic Regulations.

The review has explicitly sought from industry and other stakeholders information on any additional business compliance costs associated exclusively with the Trade Practices Cosmetic Regulations. No information on any additional compliance costs directly related to the Trade Practices Cosmetic Regulations has been provided.

Identification of Options

Regulatory and non-regulatory options have been examined for the purpose of achieving the stated objectives:

- maintain the status quo;
- remove regulation;
- amendments to the existing standard.

Industry self regulation is not likely to address the identified problem due to the nature of the industry characterised by low barriers to entry resulting in large flows of participants entering and leaving the industry. Industry self regulation works best in

¹⁵ ACCC website, accessed May 2007, WTO Working Group on the Interaction between Trade and Competition Policy (WGTCIP) was established at the Singapore Ministerial Conference in December 1996
<<http://intranet.accc.gov.au/content/index.phtml/itemId/304796>>

industries with a manageable number of identifiable, contactable, businesses that can agree and commit to medium and long term goals.

Impact Analysis

The groups likely to be affected by these proposals are:

- consumers (those who purchase and use cosmetics);
- businesses involved in the supply of cosmetics (manufacturers, importers, distributors and retailers); and
- government (including consumer product regulators).

Option 1 Maintain the status quo/leaving the current mandatory standard in place

This would preserve the mandatory standard in its current form.

Costs and benefits to consumers

The major benefit to consumers of maintaining the current standard is that it provides the existing level of safety for cosmetic users compared to no mandatory standard at all. Consumers will also continue to have access to a wide range of cosmetics and continue to be able to identify the ingredients contained in the cosmetics which they consume/use.

It is likely that the current regulation of full ingredient disclosure may also influence the type of ingredients suppliers choose to use in their cosmetics, in a way beneficial to consumers.

Costs and benefits to industry

There are costs to industry in retaining the current standard however the specific compliance costs associated with the Trade Practices Cosmetic Regulations do not appear substantial.

Unique labelling for the Australian market seems to pertain to other Australian regulations (eg trade measurements) rather than the Cosmetics Regulations.

In assessing the costs of maintaining the Cosmetic Regulations, the ACCC have sought information on what specific changes, if any, would need to be made to cosmetics labelled for the US, NZ or EU markets to comply with the Trade Practices Cosmetic Regulations. No such information has been provided. No further information from industry or other stakeholders has been provided in relation to the issue of compliance costs.

Maintenance of the status quo will maintain the same level of certainty for industry in relation to the level of product safety which is created by the labelling requirements. Also the current requirements may be beneficial to industry in reducing the level of consumer complaints and queries received which relate to cosmetic ingredients.

Costs and benefits to government

It may be considered a benefit to government that costs remain more or less unchanged if the current regulation is largely unchanged. Administration costs

associated with the Cosmetic Regulations in its current form are estimated at \$60,000 per annum.

Option 2 Remove the mandatory Cosmetics Regulations

Costs and benefits to consumers

The cosmetics industry is characterised by low barriers to entry and suppliers range from cottage industries to multi-national companies. Removing the Cosmetics Regulations would result in some international companies perhaps still supplying the information required by the current regulation, but others, such as local cottage industries may not do so. Even with removal of the Cosmetic Regulations it is noted that a percentage of products would come into Australia with labelling due to requirements in the EU and US however removing the mandatory Cosmetics standard would potentially result in a percentage of cosmetics products in the Australian market being supplied without ingredient labelling, leaving consumers unable to adequately detect or compare cosmetics product ingredients to which they may be sensitive. Also relying on labelling regulations of other countries is likely to result in customer confusion and inconsistencies in the way the ingredients lists are set out and prepared.

It could lead to amongst other things, the resurgence of the problem whereby dermatologists would be unable to quickly identify the ingredients in products which cause allergies in patients and therefore make diagnosis and treatment difficult, delayed and more time consuming.

Without ingredient labelling suppliers may not be encouraged to compete on the basis of quality of ingredients.

Costs and benefits to industry

If the mandatory standard was revoked, industry supplying the local market only (and not needing to comply with similar international labelling regimes) could benefit through a reduction of their compliance costs. However there may be a cost to industry in terms of a loss of certainty in respect of increase in costs of litigation/brand damage for cosmetics that may cause adverse consequences. Also suppliers may voluntarily continue to provide some ingredient labelling to avoid potential complaints and possible litigation from consumers. Products imported from overseas would continue to have labelling according to compliance with international requirements however as noted above there is potential for increased inconsistency in the labelling that Australian consumers will be presented with based on the differing labelling regimes available internationally.

Costs and benefits to government

Revocation of the mandatory standard would have the cost saving benefit of not requiring administration of a Cosmetic Standard by the ACCC (in the amount of approximately \$60,000 per annum).

Option 3 Amendments to the current regulations

A further option to consider is what changes may be necessary to enhance the effectiveness of the Cosmetic Regulations.

1. Request to change the definition of flavour in Regulation 3 to use the 2006 INCI Dictionary definition instead.

This requested amendment would replace the current definition of flavour in Regulation 3 of the Cosmetic Regulations with the International Nomenclature of Cosmetic Ingredients (INCI) definition. INCI is a system for naming cosmetic ingredients that is multilingual, multinational and based on Latin. The INCI system forms the basis of the International Cosmetic Ingredient Dictionary and Handbook (the INCI Dictionary).

The current definition of flavour in Regulation 3 “means a substance used solely to impart a taste to a cosmetic product.”

Regulation 5 (8) provides a flavour or flavours in a cosmetic product must be shown in the list of product’s ingredients by including in the list:

- (a) the word “flavour”, “flavours”, “aroma” or “aromas” or
- (b) the ingredients in the flavour or flavours.

In the 2006 INCI Dictionary flavour and aroma are defined as “names that are used to identify that a product contains a material or combination of materials to produce or to mask a particular flavour.”¹⁶ The terms ‘flavour’ and ‘aroma’ are used as INCI labelling names in the US and EU respectively.¹⁷

The preliminary view in the draft RIS was that changing the definition of flavour may broaden it so that instead of meaning strictly a substance that *solely* imparts taste to a product, the proposed INCI definition may allow flavour to be any product that contains a material or combination of materials, used to produce or to mask a particular flavour even if it also has other effects. These ingredients, some possibly with other effects apart from imparting taste that nevertheless qualified as flavour, would not have to be listed in the ingredients by virtue of Regulation 5(7)(b).

Any concern about the definition being broadened is mitigated by a number of considerations. Firstly, there are some existing safeguards, NICNAS regulate the ingredients in cosmetics and importers and manufacturers of cosmetic products in Australia are subject to regulation by NICNAS. New cosmetic ingredients (not on the Australian Inventory of Chemical Substances (AICS)) are subject to notification and assessment unless they qualify for an exemption. Companies and/or individuals who are introducing (importing or manufacturing) cosmetic ingredients or importing cosmetic products must be registered with NICNAS. AICS is a key tool which lists the chemicals that are available for use in Australia. Some chemicals may only be available for specific/conditional use.

¹⁶ Tara E Gottschalck, & G N McEwen, The Cosmetic, Toiletry and Fragrance Association, *International Cosmetic Ingredient Dictionary and Handbook*, Eleventh Edition, Volume 1, 2006, pg xviii introduction
¹⁷ ibid

The ACCC role in provision of the Cosmetic labelling standard is to provide consumers with information as to the ingredients so as to avoid ingredients which they may have sensitivity too. The requirement to have the words flavour and fragrance on cosmetic products, enables consumers with sensitivities to use flavour and fragrance free products in order to protect themselves from adverse reaction.

In the EU known allergens in fragrance are restricted and must be labelled.

It is also noted that since the EU introduced a requirement for 26 known human allergens to be listed in fragrance on products, there has been some issues and unforeseen consequences. A Recent study provides the opinion that that the decision of the EU on labelling 26 compounds should be revised. "Some manufacturers of cosmetics have decided to use none of the '26 annex compounds' but other compounds instead which do not need to be labelled." However the research group points out "these alternative fragrance compounds may be less well studied from a toxicological point of view and as they are mostly unknown to dermatologists they are not patch tested and possible contact allergy remains undetected." "In summary prudent labelling must take into account both the risk profile of the respective compound, and subsequent replacement policies of manufacturers which may in turn have serious implications for consumer safety."¹⁸

Independent from international regulation of cosmetics, the fragrance industry is to some extent self regulated through the Code of Practice of the International Fragrance Association (IFRA). Australia is a member of the IFRA. IFRA issues recommendations for the safe use of fragrance ingredients which are published in the IFRA Code of Practice and its guidelines. The most important reason for quantitative restrictions is skin sensitisation. Restrictions in use are recommended for a number of fragrance ingredients with sensitising potential.¹⁹ However it is noted that the main focus of the Code has been on experimental evidence of sensitisation in healthy human volunteers, which means that secondary prevention of clinical disease in sensitised consumers is not considered in the Code of Practice²⁰

Based on the information available, it is considered that the benefits of adopting the international definition of flavour outweighs any detriment.

¹⁸ Department of Dermatology/Klinikum Dortmund, Germany, *Sensitization to 26 fragrances to be labelled according to current European regulation Results of the IVDK and review of literature*, Contact Dermatitis 2007:57: 1-10, accepted for publication 19 December 2006, p.7

¹⁹ The Scientific Committee on Cosmetic Products and Non Food Products intended for consumers (SCCNFP), *Opinion Concerning Fragrance Allergy in Consumers, A Review of the Problem Analysis of the need for appropriate consumer information and identification of consumer allergens*, Adopted by the SCCNFP during plenary session of 8 December 1999, viewed September 2007, <http://ec.europa.eu/health/ph_risk/committees/sccp/sccp_opinions_en.htm>

²⁰ The Scientific Committee on Cosmetic Products and Non Food Products intended for consumers (SCCNFP), *Opinion Concerning Fragrance Allergy in Consumers, A Review of the Problem Analysis of the need for appropriate consumer information and identification of consumer allergens*, Adopted by the SCCNFP during plenary session of 8 December 1999, viewed September 2007, pg24

2. Request to exempt industrial hand cleaners under Regulation 4

This requested amendment proposes that ‘industrial hand cleaners’ be exempt from the Cosmetic Regulations pursuant to Regulation 4.

The Cosmetic Standard is made pursuant to section 65D of the Trade Practices Act 1974 which provides that a corporation in trade or commerce that supplies goods intended to be used, or of a kind likely to be used, by consumers to which a Product Safety Standard exists must comply with that Standard.

Industry submissions have suggested that industrial hand cleaners for specific use in workplaces are not consumer products and upon consideration of submissions received it is considered that industrial hand cleaners when used in the work place and transformed in business in the course of the process of production or manufacture, or in the course of repairing or treating other goods or repairing or treating fixtures²¹, will not be consumer products and not subject to the labelling requirements of the Cosmetic Regulations.

In other circumstances where industrial hand cleaners are likely to be used by consumers they will be subject to the labelling requirements of the Cosmetic Regulations.²²

Submissions in favour of this exemption suggested that there was currently duplication in the regulation of industrial hand cleaners as they had to meet labelling requirements pursuant to the Occupational Health and Safety hazardous chemicals framework, as well as those of the Cosmetic Regulations. Inquiries have indicated that the hazardous chemical framework leaves a gap for products in the workplace that are non hazardous. Industrial hand cleaners in some circumstances may not be deemed to have any hazardous substances and hence the supplier may not list the non hazardous substances on a Material Safety Data Sheet (MSDS).

The National Code of Practice for the labelling of workplace substances [NOHSC:2012 (1994)] states that the labelling system for the hazardous chemical framework has been designed to be complementary to existing labelling systems (rather than in substitution).²³

²¹ Section 4B of the Act defines consumer as:

A person (including a corporation) will be a consumer in relation to particular goods if either:

- the goods are priced at \$40,000 or less; or
- the goods are priced in excess of \$40,000 but are of a kind ordinarily acquired for personal, domestic or household consumption or in the case of vehicles...

and

they are not purchased for either:

- resale or
- using them up or transforming them in business in the course of the process of production or manufacture, or in the course of repairing or treating other goods or repairing or treating fixtures.

A person (including a corporation) will be a consumer in relation to particular services if either:

- the services cost \$40,000 or less or
- the cost of the services exceeded \$40,000 but the services are of a kind usually purchased for personal, domestic or household use or consumption.

²² *ibid*

²³ Practice for the Labelling of Workplace Hazardous Substances (NOHSC:2012 (1994) Chapter 3 pg 3 – 3.1

It is considered that industrial hand cleaners in most circumstances are not within the scope of the current Cosmetics Regulations and hence there is no need to explicitly exempt them from the Cosmetics Regulations.

3. Industry submit that parfum and aroma are now in the INCI dictionary so that they should no longer need to be listed as acceptable terms

This requested amendment proposes the deletion of the terms parfum and aroma from the Cosmetic Regulations. Parfum is referred to in Regulation 5(8)(a) and Aroma/s is referred to in Regulation 5(7)(a).

Regulation 5(7) states that “a flavour or flavours” and regulation 5(8) states the words “fragrance, fragrances” in a cosmetic product must be shown in the list of a products ingredients. Even though Parfum, Fragrance, Flavor and Aroma are in the INCI dictionary it is considered that the presence of Regulations 5(7)(a) and 5(8)(a) in the Cosmetics Regulations is likely to assist suppliers in attempting to comply with the Cosmetics Regulations by explicitly stating how these ingredients can be listed by the use of certain words; or in the alternative by listing the ingredients in the fragrance or flavour (Regulation 5(7)(b) and 5(8)(b)). Knowing what information is required on the label by consulting the regulation itself without having to resort to secondary sources such as the INCI dictionary provides clarity as to what terms can be used and will be particularly helpful to smaller cottage industries which are an important feature of the cosmetics industry.

Parfum, Fragrance, Flavor and Aroma are used as INCI labelling names in the US and EU respectively.²⁴

4. Industry request that a list of active ingredients also be allowed on the product in addition to the ingredient labelling for cosmetic products

This requested amendment proposes that the Cosmetic Regulations be amended to permit a list of active ingredients in addition to the current labelling required by the Cosmetic Regulations.

Active ingredient may be defined as the ingredient that is responsible for producing the desired effect, of a mixture of ingredients for giving the product its main characteristic. The active ingredient is not necessarily the most common ingredient in a product.²⁵ An active ingredient may also be defined as an ingredient which has a technical and functional effect and is likely to be present in significant levels.

Regulation 6(1) provides that a list of ingredients must be:

- (a) prominently shown; and
- (b) clearly legible.

An industry representative requested the following addition to Regulation 6:

²⁴ Tara E Gottschalck, & G N McEwen, The Cosmetic, Toiletry and Fragrance Association, *International Cosmetic Ingredient Dictionary and Handbook*, Eleventh Edition, Volume 1, 2006, xviii - introduction

²⁵NOVA science in the news website accessed May 2007 – published by Australian Academy of Science
<<http://www.science.org.au/nova/083/083glo.htm>>

(4) A separate list of names of all active ingredients in the product may be marked on the container.

Including a separate list of names of all active ingredients is not precluded under the current Cosmetic Regulations, and that the regulation need not be amended to permit the proposal.

Such an amendment may also be difficult to justify when the purpose of the Cosmetic Regulations is considered. The amendment does not appear to play a role in preventing or reducing the risk of injury to any person as it does not provide new information not already contained on the label.

5.Request for a deeming provision

A request was made for the review to consider a clause exempting fully imported products intended for use as cosmetics which meet labelling requirements of the EU, US, Canada and or NZ from the Trade Practices Cosmetic Regulations. Analysis of the introduction of a deeming provision suggests that such an amendment would be impractical in terms of ensuring ongoing protection for Australian consumers, especially noting the current state of flux of cosmetic regulation, particularly in NZ and the EU. The Environmental Risk Management Authority (ERMA) is currently conducting a review of the NZ Cosmetic Group Standard and this NZ Standard may change in 2008. Suppliers in NZ can voluntarily comply with the regulations of some overseas jurisdictions including Australia.

If a deeming provision is adopted there will be a number of differing international standards which could be relevant and establishing non compliance with overseas labelling requirements would create a number of significant difficulties. Australian regulators would be required to become familiar with a number of overseas cosmetic labelling regulations in order to identify cosmetics labelling non compliance in Australia.

An amendment to the Trade Practices Cosmetic Regulations, that deemed cosmetics complying with overseas labelling requirements to be compliant with Trade Practices Cosmetic Regulations would require that the labelling requirements of several overseas jurisdictions be referenced as acceptable alternatives to the Trade Practices Cosmetics Regulation.

The ACCC would be unable to respond if there was a breach to the Trade Practices Cosmetic Regulations because provided the product complied with the specified overseas regulation/s, it would be deemed to comply with the Trade Practices Cosmetic Regulations and therefore exempted from its application. The only way the ACCC could take action under the Trade Practices Cosmetic Regulations would be if the ACCC could prove that the product did not comply with the overseas labelling requirement/s it is said to comply with, so that the deemed compliance with Trade Practices Cosmetic Regulations is prevented. This could hamper the ACCC's ability to protect Australian consumers in relation to sub standard/mis labelled cosmetic products.

Costs and benefits to industry

It is considered that the Cosmetics Regulation does not impose relabelling requirements/costs on imported cosmetics products.

Like the EU and the US, the Trade Practices Cosmetic Regulations require a full ingredient list. Market inquiries indicated that the Trade Practices Regulations do not result in any relabelling costs to suppliers importing overseas brands to Australia. Despite requests no information has been provided by industry to substantiate a claim that the Trade Practices Cosmetic Regulation results in any relabelling costs. Relabelling costs attributed by a stakeholder to complying with the Trade Practices Cosmetic Regulations were found to be imposed by trades and measurement regulations unrelated to the Cosmetics Regulation.

There are costs associated with identifying and understanding the nature of the Cosmetics Regulation. The introduction of a deeming provision may reduce some of these costs as suppliers no longer need to comprehend the Cosmetics Regulation. However it is considered that as this imposes very minimal cost to industry it is considered that adopting a deeming provision will not realise discernable cost savings to industry.

Costs and benefits to consumers

An effective Trade Practices Cosmetic Regulation is considered to be of significant benefit to Australian consumers.

As demonstrated, a deeming provision would mean that consumer protection relied on overseas regulations. Although the EU and US products are likely to continue to require full ingredient labelling there may be some differences in the labels which may cause consumer confusion and or injury. In the case of NZ imports one interpretation of their current regulatory regime is that only hazardous substances are labelled. In this case there is the potential for cosmetics imported from NZ to have no labelling at all.

A possible benefit to consumers of including a deeming provision may be a wider range of cosmetics being imported into Australia. However there is no information to suggest that the Trade Practices Cosmetics Regulations substantially increase costs for importers of cosmetics. Further, no evidence has been provided to the Cosmetics review that the Cosmetics Regulation inhibits cosmetics imports. It is noted that there is a wide range of imported cosmetics currently available in Australia and a large amount of cosmetics in Australia are imported.

Summary Consultation Views

A consumer group has advocated mandatory labelling of major allergens within the chemical compositions contained under the words flavour, aroma, parfum and fragrance to be labelled. This issue has been discussed under the 'change to the definition of flavour'. In summary, the purpose of the Cosmetic Regulations is satisfied in that consumers have the opportunity to avoid potential allergies caused by fragrance and flavour by identifying on the product label that it contains flavour or fragrance. There are many ingredients that may make up a flavour or fragrance hence

it may be impractical to require suppliers to list them all. The EU has recently had a requirement to list 26 known allergens in fragrance, however this has not been without concerns being raised and there have been requests for the list to be reviewed. Also a change to the definition of flavour may not in practice change what is put under the terms flavour and fragrance.

A number of state government consumer agencies and other government regulators have agreed with the proposals in the draft RIS. The Australian Society of Cosmetic Chemists (or an Association of Chemists) has agreed with the views in the draft RIS and are in favour of the adoption of the INCI definition of flavour.

One business organisation has supported the peak cosmetic industry body's view with regards to an exemption for industrial hand cleaners.

A large Australian supermarket retailer is of the view that "there is an ongoing need for cosmetic regulation in Australia to ensure that consumers have access to sufficient information about cosmetic ingredients in order to reduce potential risk of injury." The retailer also noted that if active ingredients are to be listed on products the suppliers should also list the percentage of the active ingredient. It is considered that active ingredients and their percentage do not need to be mandated in order to satisfy the purpose of the Cosmetic Regulations.

A toy distributor who sells children's cosmetics supported regulatory option 3 to allow for a change to the definition of flavour.

Costs and benefits of proposed minor amendment to definition of flavour in Cosmetics Regulations

Costs and benefits to consumers

A change to the definition of flavour is not likely to impose any substantial cost on consumers and any potential minor cost (in terms of the potential for more ingredients to be listed under the term flavour) are balanced against the safeguards provided by other regulatory regimes.

Costs and benefits to industry

The INCI dictionary appears to be a reference widely used and accepted internationally within the industry. Changing the definition to the INCI dictionary version has the benefit to industry and government of bringing the Australian mandatory standard in line with international standards. The INCI dictionary may help create consistency of labelling for consumers throughout the world. For these reasons, this minor amendment is acceptable.

Costs and benefits to government

No changes in administration costs or benefits to government as a result of this amendment, have been identified.

The potential detriment to consumers of a change to the definition of flavour, has been balanced against the benefit of a having a definition which aligns with the definition used in major markets, the EU and the US.

Conclusion and recommendation

Option 3, is the most favourable option which allows for minor amendment to the Cosmetic Regulations in order to keep the Cosmetic Regulations up to date.

It is proposed that the definition of flavour in Regulation 3 be changed to reflect the 2006 INCI dictionary definition. No other minor amendments have been considered necessary. There is no need to amend to the Cosmetic Regulations in order to address the labelling issue with regards industrial hand cleaners. Active ingredients may be added to cosmetic labelling in addition to the labelling requirements under the Cosmetic Regulations without this requirement being mandated.

Implementation and Review

An updated mandatory standard would become effective the day after registration on the Federal Register of Legislative Instruments and be subject to review five years later. Once the new EU Cosmetic legislation is implemented in 2009/2010 this may necessitate a reconsideration of the Trade Practices Cosmetic Regulations.