CTFA
Cosmetic, Toiletry, and Fragrance Association

Cosmetic Toiletry and Fragrance Association of New Zealand Inc

Submission to National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Therapeutic Goods Administration (TGA)

On

Review of Cosmetic – Therapeutic Interface

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Background Information

The Cosmetic Toiletry and Fragrances Association of New Zealand Inc. (CTFA) is the pre-eminent membership organisation representing cosmetic companies within New Zealand. The CTFA is affiliated to similar bodies internationally and communicates with such bodies to ensure international harmonisation where possible.

The present membership consists of the majority of Cosmetic, Toiletry and Fragrance manufacturers and/or distributors of such products within New Zealand and by value around 90% of the New Zealand Cosmetic market.
The Cosmetics industry in New Zealand generates around $150 million in exports across a range of product types ranging from traditional cosmetic products to natural ingredient or unique New Zealand cosmetics. These products are also sold in the domestic market.

Membership is voluntary and governed by a Code of Ethics for market conduct.

A Cosmetic Code of Practice is well developed covering Good Manufacturing Practice, including voluntary manufacturing guidelines, handling, storage and labelling practices for our member companies to ensure compliance with the Hazardous Substances and New Organisms (HSNO) legislation.
This document is publicly available and will be an approved code under the HSNO legislation

Currently the CTFA New Zealand has 68 members included sub groups such Beauty and Hair Salon Marketers.

The CTFA and its members support the charity "Look Good Feel Better" by both fund raising and providing products in excess of $2.5 million dollars per annum. The charity provides annually workshops for more than 2000 women with cancer on how dealing with the effects of the treatment each year.

The CTFA works in close cooperation with groups such as the Direct Sellers Association and the Employers and Manufacturers Association on issues of common interest. Direct Sellers account for around 20% of Cosmetic sales in New Zealand and for a significant component of the exports made.

Cosmetics are defined by Section 2 of the Medicines Act 1981. A cosmetic means any substance or mixture of substances used or represented for use for the purpose of beautifying, improving, protecting, altering , or cleansing the hair, skin or complexion of human beings, and includes:

- Any perfume
- Any Deodorants
- Any insect repellent
- Any dusting powder

Products range from the well understood perfumes, colour and skincare products to products such as toothpaste and anti-dandruff shampoos.

Around 90% of cosmetic products sold in New Zealand are imported. These are manufactured to world best practice and accepted Good Manufacturing Practice standards in Europe and the USA.

Submission

The Current Australian Position

The current regulation of Sunscreens in Australia requires ingredient approval, GMP Auditing, labelling and prescriptive acceptable claims, and this is quite unacceptable from a New Zealand industry perspective.

We believe that there is no scientific, public health and safety argument or commercial basis for the continued regulation that can reasonably be substantiated or justified in New Zealand with its long experience of no adverse effects from marketing and advertising self regulation.

Cosmetics are not considered as medicines anywhere in the world. Where there are borderline categories that need to be individually defined in America and Canada controls arose out of the 1938 Food Drug and Cosmetics Act in the USA with the monograph system for borderline products. In Europe a more modern system was implemented in 1976 with a Cosmetics Directive using positive and negative lists to control ingredients.
Australia is the most restrictive with pre-clearance through a licensing and manufacturing auditing system and this is now no longer best practice. The uneventful history of sunscreen products that we have in New Zealand leads us to believe that Australia has placed undue emphasis on its regulatory process.

Regardless of the recommendations made in this review, we believe there is no basis for continuation of the current Australian regulatory imposts for sunscreens or mandatory requirements for other cosmetic products claims, labelling and GMP under the Therapeutic Goods Authority.

The Changed Recommended.

We do not accept that the recommendations should in any way be accepted or carried forward to the Joint Agency.

The CTFA New Zealand supports Trans-Tasman harmonisation to ensure both countries get the best possible outcomes from a joint regulatory environment however we do not see the recommendations made in this review as achieving this.
The recommendations are one sided and detrimental to New Zealand industry and consumer choice with only one area of benefit able to be determined for New Zealand.

THE SCIENCE AND THE REGULATION

The CTFA New Zealand makes the following points and elaborates on these in the course of this submission.

1. There is no "Regulatory Impact Statement" undertaken with this review
2. There is no diminution of public health and safety in New Zealand in the absence of a TGA based regime that would support this regime becoming part of the Joint Therapeutic Agency
3. There is a lack of scientific basis in the recommendations given
4. The impact on Trans-Tasman trade has not been considered
5. These recommendations are not representative of the lowest regulatory application
6. Regulation should be related to the degree of risk – for example what is the risk of the product not working?
7. The Joint Trans-Tasman Agency if it is to be a worlds best agency should be looking at the European Union or USA for best practice and not invent its own

Regulatory Impact Statement

There is nothing in the review document that takes into account the impact on the industry and in particular that of the New Zealand industry should these recommendations form the basis of the Joint Therapeutic Agency requirements for the cosmetic products being covered.

The first step should be to undertake this work and since this is purported to be a Trans-Tasman document look at all the impacts on both sides of the Tasman.

The cost to cosmetic companies in New Zealand would be extreme with the loss of product choice and the ability to bring better products to market.

Diminution of Public Health and Safety in New Zealand

The key issue ignored in this report is the fact that there is no diminution of public health and safety in New Zealand and therefore to advocate regulations that are intended to reduce risk to the public, cannot be substantiated.

If there are areas where the health and safety of New Zealanders is less due to the lack of such regulation, then perhaps the argument could be made for some regulation although it is doubtful that the level of regulation currently applied in Australia or even the reduced level of regulation proposed in the report would be necessary.

We would argue "where are the harmed consumers or the misled consumers in New Zealand?"

On the last question of misleading consumers, both countries have trade practices legislation (Fair Trading Act for New Zealand) and that is the right and proper place for such controls. This need not be the concern of a separate agency.

Lack of Scientific Basis to Recommendations

If the recommendations are based on science then they would make similar recommendations based on risk for all areas. How is toothpaste, an oral use cosmetic any less risk than a Sunscreen which is topically applied?

The recommendations must be consistent at least and therefore those contained in this report are more opinion than science and consistency not demonstrated.

Impact on Trans-Tasman Trade

While there may be some argument that the regulation under a joint agency will make for simpler compliance for those involved in Trans-Tasman Trade, we believe there is no benefit involved for New Zealand.
Those companies already involved in supplying products to Australia, comply with the existing regulatory environment by either contracting out work to approved third parties where their plants can not meet the excessively strict therapeutic GMP Audit requirements or have already upgraded to meet those requirements where volumes justify such upgrades. Such costs are considered unreasonable and excessive for cosmetic products. You should note that since 1982 the Division of Clinical Services of the New Zealand Department of Health (now Medsafe) issued a Code of GMP for the Manufacture and Packaging of Cosmetics, commonly called the Blue Book. This voluntary compliance code was endorsed by the CTFA New Zealand and the Department of Health has used this Code as the basis of inspecting factories making cosmetics and toiletries. The review did not pick up this voluntary Code and New Zealand's industries existing compliance to it.

There are, however a range of products that are sold in New Zealand that are not supplied in Australia simply because of the current TGA sunscreen requirements including mandatory claims or approval requirements. These products include a wider range of sunscreen products and anti-bacterial soaps. There has been no assessment of the impact of imposing the proposals in this report on New Zealand under the Joint Therapeutics Agency against the purported benefits.
This impact study must be assessed whether independently or as part of the regulatory impact study.

Recommendations not representative of the lowest regulatory application

Where regulation is required, it must be based on COAG principles and the least regulatory intervention required assessed, producing the desired outcomes. The recommendations in the review are not based on this and are instead some reductions on existing regulatory controls based on continuing and maintaining the established regime and the present overall structure.

If COAG was applied to the Cosmetics in this review then all highlighted in the review would be treated the same as other countries treat them under "Cosmetics" and nothing more.

The New Zealand Cosmetic regime being established under HSNO picks up worlds best practice and recognises compliance to appropriate regimes as being compliance for New Zealand. This includes the European Unions Cosmetic Directive where all the interface products of this review are not only controlled as Cosmetics, but use GMP is appropriate to the Cosmetic industry and not to the Pharmaceutical industry. We do not support mandatory GMP but do support voluntary compliance to appropriate GMP which can be demonstrated to have worked for many years already within New Zealand.

Acceptance of such international standards is imperative in the global marketplace where products are manufactured for international markets and not solely for one small market

such as New Zealand or Australia. Even the combined size of both markets barely rates notice against the scale of markets such as the European Union or the USA and to ignore them damages competitive forces from operating and ensuring our domestic producers are able to match the worlds best.

Regulation should be related to risk

Fundamentally this comes back to risk and regulation to the level of risk involved. The risk of an anti-acne cream/cleanser not working is the acne will not reduce or disappear and the purchaser of the product will not buy that product again. If that were the case then the Fair Trading Act in New Zealand and the Trade Practices Act in Australia is quite capable of dealing with misleading the consumer and the penalties are equally adequate.

If a sunscreen excipient is risky then virtually every cosmetic product has the same degree of risk since many of the ingredients are often common with the exception of those that apply to the SPF being achieved. Therefore why do we require under the TGA/Joint Agency, a full reassessment when a particular Herbal Extract or Fragrance is added when the properties of the product's SPF have not changed and the same extract or fragrance may have been widely used elsewhere in the cosmetics products and assessed already by NICNAS or the ERMA.

To regulate such products other than as a "Cosmetic" is not managing risk, it is far more than this! It does not improve public health and safety, it just adds costs. Excessive regulation restricts the availability of new products that may perform better, but are just not cost effective to introduce to the market under the proposed regime.

Joint Therapeutic Agency and World's Best Practice

The world's best practice is widely acknowledged as being the European Union under the Cosmetic Directive. There is equally good practice available from the US under the monographs and to ignore these agencies and regimes in favour of a stand alone agency even for a limited number of cosmetic products, is not adopting worlds best practice but applying a non tariff barrier and anti-competitive rules for entry into the Australian market and through the Joint Agency the New Zealand market.

There should be an automatic acceptance that products produced under those other markets' rules with it noted that New Zealand has its own voluntary Cosmetics GMP and Packaging requirements approved 23 years ago by the Department of Health and operated successfully in New Zealand over this time. The EU Industry GMP Guidelines and their forthcoming ISO standard on Cosmetics – GMP Guideline on Good Manufacturing Practice are similar.

The revised New Zealand industry based voluntary Cosmetic Code accepts existing and proposed GMP used in Europe, recognises US Monographs as acceptable and is designed to align to provide domestic manufacturers with an alternate tool to comply not only with HSNO but for supply to those markets.

World's best practice clearly demonstrates that a full approval regime for cosmetic interface products is both unnecessary and over regulation regardless of perceived therapeutic benefits.

At most, controls over active ingredients use aligned to the Cosmetic Directive should be considered under HSNO for New Zealand or NICNAS for Australia "for Cosmetic use" where appropriate, but we do not accept that these products/ingredients are required to be controlled under the Joint Agency as Therapeutics.

Specific Products Recommendation Comments

Antiperspirants

These are products whose principle purpose is to mask or hide odour and to help stop sweating there should not need to be any such category as "Exempt" as they are not a high risk product.
These will be covered in New Zealand by the HSNO legislation and should any concerns be established for any excipients this legislation is more than capable of addressing that issue through banned or restricted
The recommendation of antiperspirants being a cosmetic is therefore supported.

Anti-dandruff Shampoos

While these products are currently treated as a related product in New Zealand requiring less application for recognition under the Medicines Act, this is not ideal. We support the removal of these products from the current New Zealand related products requirements as this produces additional compliance and has the effect of reducing the market for what is a safe cosmetic product.

We do not support the need to have this as an exempt product as the difference to most shampoos is negligible and it is wiser to treat these as a sub-set of the proposed HSNO Cosmetic Code under Shampoos for appropriate controls should additional controls be necessary.

Primary Sunscreen

These are treated as Cosmetic products in many countries and to argue that Australia or New Zealand is somehow unique is a poor argument.

We believe there are already international standards like the FDA SPF static method that could be adopted now. We support the development of a single international standard to pick up the appropriate mechanisms for development, production and measurement of SPF but believe this is some time away and there is no reason to wait for this to occur.

We can find no increase per capita of the incidence of sunscreen related illness in New Zealand which is more exposed to the Ozone hole than most of Australia.

New Zealand has exposure to 50% higher levels of UVR in summer months than equivalent countries in the northern hemisphere (McKenzie et al 1999).

New Zealand however experiences less incidence of Skin Cancer than that of Australia (Australian Institute of Health Australasian Association of Cancer Registries ACT Cancer Series 28 Dec 2004). While the mortality rate shown in this document is marginally higher in New Zealand this can not be argued to be related to sunscreen use but to detection. Later data produced in the Atlas of Cancer Mortality in New Zealand shows even less difference in the mortality rate of Australia 4.8 and New Zealand 4.9 which would indicate improving education and detection is working at least as well as Australia.

Incidences of Melanoma New Zealand show a crude rate of just 45.2 per 100,000 while Australia has 51.6 per 100,000 (Table 28/Page 70 of the Series 28 document).

Such data denies the validity of the arguments for continuing the current Australian regime and proves that the greater value is in education of good sun protective behaviours (The New Zealand Cancer Control Strategy: Action Plan 2005-2010).

Therefore we would strongly argue that there is no case for regulation of this product as a Therapeutic product.

The CTFA New Zealand supports the need for both countries apply best international practice which would see the joint standard AS/NZS 2604:1998 revised to accept the measurements used for SPF elsewhere in the world and to then promote this once suitably amended for adoption as an international standard. We note however that AS/NZS2604:1998 is dated and other countries particularly the European Union, and Japan have progressed considerable in the last few years in both SPF and UVA methods.

We find there is no logic in treating these in any different way to that of other cosmetic products given the evidence of the incidence statistics and that if Australia must have a mandatory requirement then this is best served through a mandatory standard under the Trade Practices Act or the New Zealand HSNO Regulations.

We would argue that the GMP auditing of sunscreen manufacturers is overly expensive and since the recommended class 1 would maintain this status quo under the Joint Agency, it is excessive and does not reflect the real risks being managed. The Audit process does not produce any higher standard of production nor does it improve the overall health and safety of Australians as is demonstrated in the comparative data.

If this were false then the number of products that appear on the New Zealand market that are not sold in Australia due to the high cost of the application process would have experienced adverse effects within New Zealand. There is no evidence of this occurring and in fact the reverse appears so in the data quoted earlier in this submission.

If this system were to be applied to the Joint Agency then it is entirely likely that a number of top selling products will disappear from New Zealand shelves as neither the Australian or New Zealand markets warrant the costs of undertaking and meeting requirements of the recommended class 1 approval process. This is as much to the detriment of the public business since competition is in its self a form of education about safe sun behaviour.

We would argue that the current mandatory standard as applied under the current rules also adversely affects the ability to market better products in Australia should those companies wish to undertake the regulatory hurdles applied for placing a primary sunscreen on the Australian market.

New Zealand has products that genuinely have SPF60 as measured by international measurements such as those in the EU and to restrict claims to that of SPF30 is misleading the consumer. We recognise that once over this level, the exponential increase of protection reduces however that is not a reason to restrict either these products availability or consumers from choosing those products on the basis of the higher protection. We encourage New Zealanders to use sunscreen and while SPF30 may be adequate to protect most skin types, the higher the number the better the protection for those skin types that are particularly sensitive.

Ensuring that higher number SPF are both available and consumers are aware of them improves the health and safety of New Zealanders and bureaucratic controls should not get in the way of the industry delivering such improvements to consumers. We believe that it may even be that the availability of higher level SPF sunscreens in New Zealand assists attaining the lower incidence of skin cancers.

We question why excipients must be approved by the TGA for safety when the same ingredients are used widely in many other products with absolute safety.

Sunscreens are not cures and they do not treat cancer, they only provide a barrier to the harmful UV rays that cause skin cancer.

They do get applied widely to the body; however so do many other cosmetics products such as body washes and moisturisers, and to argue this as a reason for increased regulation is not scientific argument. All cosmetic ingredients are risk assessed by Authorities in Europe, America, in Australia under NICNAS and in New Zealand under HSNO and duplicating risk assessment processes for these ingredients when used in conjunction with Sunscreens is unnecessary regulation and compliance costs for no additional public safety benefits.

- We recommend that this recommendation be revised to include a revision of the standard AS/NZS 2604:1998 to accept international measurements for static SPF if a single international standard is developed that this then be used to replace AS/NZS 2604.1998
- We recommend that once this revision of the standard is done, that Australia then insert this standard into the Trade Practices Act as a mandatory standard with New Zealand to use the HSNO Act to apply appropriate similar controls.
- We recommend that Sunscreens not be class 1 but be excluded from such controls and treated as a cosmetic in both countries under the Joint Agency.
- We recommend that should any form of regulation still be considered after our primary recommendations, that excipients be removed from the assessment process for sunscreens. This recommendation does not lessen our belief in our first three recommendations.

Moisturisers with Secondary Sunscreen

We strongly support this change being made for secondary sunscreens immediately for Australia however we do not believe this is far enough from a New Zealand perspective. What is the scientific basis for SPF20 and why not SPF30+ or even any level SPF since this is not the primary reason why the consumer is purchasing the moisturiser.

There is no need to require any form of disclaimer on such products, as to require this, is to add compliance costs to protect against a risk that does not exist. This comes back to the fundamental question of what risk is being guarded against and what is the least regulatory intervention required to achieve this.

There is already an advertising code developed which will clearly cover these issues without requiring some special conditions to apply. Therefore we support the removal of any form of disclaimers.

Sunscreens with SPF <4

This category should disappear if the recommendations made earlier in this submission are adopted.

Sunscreens for Lip Use or as tinted facial makeup

The CTFA research establishes clearly that while these products are cosmetics, the effect of sun protection on areas such as lips does not need to be as great as other parts of the body. Such products however are purchased as lip protection and colour and not primarily for sunscreen protection. Therefore keeping these products as cosmetics is strongly supported.

Antibacterial Skin Washes

The CTFA New Zealand can not support the recommendation made in this report. There is no evidence of bacterial resistance ever occurring with these products and there is strong evidence in New Zealand that consumers are very aware of the differences when purchasing anti-bacterial skin wash products for domestic use.
If there were any truth in the argument of bacterial resistance then the correct labelling of the product will not change this since it is quite possible to sell a antibacterial skin wash in Australia labelled as a liquid soap or the like as long as the word "Antibacterial" is omitted. This argument is nonsense and should be completely disregarded.

We believe there need to be a clear delineation between products sold for domestic use and those sold for hospital or clinical uses where some additional form of assessment may be necessary.
Domestic products intended for domestic use should be classed as a cosmetic, and only those intended for Hospital or clinical use should need to be class II.

Such products have been sold for many years in New Zealand without issue and the District Health Boards have undertaken the approval system to ensure such products are suitable for use in their hospitals and medical facilities. We see no reason to change this system and add both restrictive elements to domestic products and additional costs to all anti-bacterial skin wash products.

We believe that Australia should be adopting the same stance and using at least a tiered system until these products are bought under a Joint Agency with domestic antibacterial skin washes excluded as cosmetics under the TGA. There is no deception or consumer detriment in allowing domestic antibacterial skin washes to be so labelled and accurately describe what they are.

Anti-Acne Skin Cleanser

Anti Acne Skin Cleansers are primarily a cosmetic product and to place them in Class II is excessive management of what at worst is the cleanser not working to kill acne causing bacteria. The regulation of this must be on the basis of real risk.

We do not accept that these products need to be treated any differently to Anti-dandruff shampoos given the level of risk involved and do not support anything less than exclusion.

Mouthwashes

We believe these are cosmetic products and that to call them anything else is excessive regulation. The current New Zealand system of F>100ppm F or claims for Gingivitis is more than adequate and adopting the lowest regulatory intervention model in any joint agency.

Toothpastes Fluoride

We agree with the proposal as being sensible.

Toothpastes Desensitising

We believe these should be dealt with as cosmetic products in a similar manner to Mouthwashes. Again it is about the risk to the public. These products are well known and do not need to be treated any differently to that of normal toothpastes.

Blemish Sticks

We accept the recommendations on these as cosmetics.

Personal Lubricants

These should only be cosmetics.

Unless these were biocidal lubricants designed and labelled for a particular treatment purpose where they might be considered as class I and listable there is no reasonable way to assess them as anything other than a cosmetic.

The difficulty of when a lubricant is in fact a lubricant is difficult to identify since many products may be used in this way but not be primarily sold for that purpose.
Vaseline is sold as a multipurpose product ranging from lubricant to skin protection for babies. It is used by sports people to prevent chaffing but it is hard to class that use as a personal lubricant.

Therefore any argument other than a cosmetic classification of these products can not be considered.