C T F A

THE COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION OF AUSTRALIA INC.
ABN 90 187 366 173

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Dear Pio and Margaret

Re: Response to the Recommendations of the Regulation of Products at the Interface between Cosmetics and Therapeutic Goods (NEWGREEN REVIEW)

Thank you for inviting the Cosmetic Toiletry and Fragrance Association to comment on the Review of the Regulation of Products at the Interface between Cosmetics and Therapeutic Goods (Newgreen Review) 18 March 2005.

Introduction

CTFA wishes to compliment the author and those who commissioned the Newgreen Review (Review) on a comprehensive and pragmatic draft discussion paper. Overall we believe the recommendations are a welcome compromise to the regulatory requirements with no change in safety risk management that the CTFA and others have discussed with the TGA over a number of years.

The LRCC process has been the catalyst for questioning the interface product classifications with the aim to reconsider the appropriate regulatory controls and harmonise them with international standards. The unique timing of the establishment of the Joint Agency between Australia and New Zealand has complicated but at the same time created an opportunity again to review the appropriate level of regulation needed.

It is so easy to stick with the status quo and create doubt by emphasising what might happen in extreme cases in theory and demonise change but usually entrenched vested interest is behind such scare mongering approaches. In large part the Newgreen Review has seen through this type of argument and as such should seriously be acknowledged as the way forward. We ask that as decision makers now review comments as a result of this further round of consultation be equally objective and cognisant of the submissions previously made.

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In fact, there are two recent examples of a practical approach to regulation that come to mind, which should be noted.

(a) The success of what has already been delivered by the LRCC process itself, and

(b) The principles applied to common scheduling between Australia and New Zealand over the last few years.

It should be noted that these examples of change have produced no adverse effects, nor any diminution of health and safety standards. These changes have been well received by industry and importantly, they were driven by the regulators.

Noting these successes and approaches, the real question is *"Have the recommendations of this Review gone far enough to apply a minimum but appropriate level of effective regulatory control for products that have an excellent record of performance and safety?"*

CTFA believes that with no evidence of public health adverse reports, the Review's recommendations could have gone further particularly, in the categories of antidandruff shampoos, antibacterial skin washes, soaps and wipes. However, the CTFA believes this is a step in the right direction and seeks favourable consideration be given to our comments herein.

Consultations and Timings

It is important to note that extensive consultations have already been had as part of the inclusive process undertaken by the author as part of the Terms of Reference. The Review has been a long time in preparation. We would like to note that the author has consulted with more organisations, in more depth and over a longer period of time than the original terms of reference indicated. CTFA acknowledges the degree of difficulty faced in aligning recommendations to cover both Australia and New Zealand.

We wish it to be recorded that the letters to stakeholders advising of the appointment of Mr David Newgreen, who would undertake the Review were issued on 3 May 2004, calling for preliminary comment by 28 May 2004. In depth interviews were then conducted and submissions proceeded from that point. Consultation has been extensive in fact, the Review took until 18 March 2005 to be issued. We understand that this draft had been substantially discussed by the regulators prior to release to industry and other stakeholders for further comment. In light of this long gestation period it is only the detail and implementation that should now be the focus of further consultation and action.

This round of the consultative process should not result in significant changes to the recommendations now proposed. We believe that industry associations and government regulators have had extensive opportunities to consult and lobby.

Guiding Principles and Terms of Reference

We think the six guiding principles formed an appropriate benchmark for the Review. We note however, that one of the guiding principles was that regulatory reform should be undertaken in accordance with the 1997 Council of Australian Government Principles and Guidelines (COAG) which support minimum effective regulation.

These principles are reflected in the many consultation steps undertaken. However, the Review does not seem to ask the question of what is the minimum level of regulation necessary to maintain and enhance the protection of public heath and environmental standards for product categories of this Interface Review. We believe that the Review was approached, from what is current in Australia rather than what is the minimum effective regulation needed, taking into account world best regulatory practice and the successful living example for these categories of consumer products in New Zealand where most are classified as cosmetics.

We also note that under the Joint Agency, there is an opportunity to re-evaluate the classification of some therapeutic goods, on the basis of risks associated with the goods, into Class I and Class II medicines. This would not duplicate the existing classifications of listed and registered products particularly in relation to products classified on the basis of ingredients included in a published list of permitted ingredients. The defaulting of products as registered or Class II category medicines only because they are not covered by the published lists or conditions, rather than on the basis of the risk associated with the goods is an area that needs further discussion but is more appropriately in the context of comments on the Description of the Joint Regulatory Scheme rather than in this response.

To quote from that Description document, "The classification of a medicine will be based on a number of factors, including:

- The intrinsic risk of the product (e.g. the toxicity of its ingredients).
- Risks associated with the quality of the product (e.g. requirements for sterility).
- The intended use of the product".

The Document also defines the two class scheme:

- "Class I medicines are low risk and the product licensing procedure will be based on certifications made by the sponsor and the validation of key data by the Agency", and
- "Class II medicines are higher risk and the product licence procedures will be based on the evaluation of quality, safety and efficacy of the medicine undertaken by the Agency".

The Document notes that the majority of complementary medicines will be Class I medicines. A claim that "treats or prevents" should not and does not automatically classify a product as Class II.

It is useful to point out that Health Canada has recently (January 2005) reviewed the GMP requirements for their low risk category products that they call Category IV, which are almost identical to the interface products covered by the Newgreen Review. The result of the Canadian Review was to reduce the level of GMP and stability testing requirements for Category IV products. It is significant to note that another recognised authority has moved in a similar direction to the Newgreen Review recommendations.

We thought that the underlining reason for the Review and the background of the LRCC recommendation was that in dealing with this low risk category of cosmetic and cosmetic-like products, it would be more efficient to classify them and control them through the risk posed by the ingredients and concentration levels in products and the claims made. This is in line with modern risk assessment and its governance that has become mainstream corporate practice over the last 10 years. A number of products now in Class II are there because they originated as grandfathered Victorian Registration products and in going onto the ARTG in 1991, prescriptive lists were drawn up to rationalise this requirement. At that time, NICNAS although established in 1990 had not evolved to its current status as regulator of cosmetic ingredients.

There are successful examples of this approach in Europe through the EU Cosmetics Directive and to a lesser extent in New Zealand. Additionally, in Australia there is an opportunity with NICNAS and the NDPSC to increase regulatory efficiency with no diminished assurance of safety, particularly when both regulatory/control arms of consumer assurance and protection, fall under the umbrella of the Department of Health and Ageing and the Australian Competition and Consumer Commission (ACCC). We feel this Review has missed these facts in 2005.

It should also be noted that consumers can be better informed when products have ingredient labelling as all cosmetics are required to have. Full ingredient labelling is widely supported by Dermatologists with a preference for the INCI nomenclature system. With **all** ingredients listed and NICNAS responsible to ensure **all** ingredients, including excipients, are safety assessed, consumers are better off, administration more efficient and with speedier product availability on the market.

Better information and wider choice is a constant demand by the consumers.

We note that Health Canada allows ingredient labelling on their Category IV products and the naming of the ingredients follows the International Cosmetic Ingredient Dictionary Nomenclature.

Our comments on each of the Review Recommendations are as follows.

Recommendation 1:

Cosmetic Claims Guidelines

Cosmetics claims guidelines should be established by the Joint Agency, in consultation with stakeholders and other regulators, to clarify the distinction between cosmetics and therapeutic products. These guidelines should be underpinned by legislation if necessary.

CTFA Comment:
The CTFA has consistently stated that once the cosmetic/therapeutic interface exercise was completed then revision of the Cosmetic Claims Guidelines would be an early priority.

We believe that the Canadian Claims Guidelines represent best practice as they were when their original guidelines were used to write the Australian Cosmetic Claims Guidelines in 1997. Canada has moved regularly to update their guidelines and in the process removed the unnecessary centre column many years ago.

A regular update mechanism as the Canadian Claims Guidelines have is a common sense requirement that should be built into any Australian Cosmetic Guidelines revision.

We would like to question the suggestion in the Review that the ownership of this process be under the Joint Agency as we see this more as a "Cosmetic Guidelines" not "Therapeutic Products Guidelines". We think this Guideline should be a Trade Practices Act issue.

This is consistent with the full ingredient labelling requirements for cosmetics. It is consistent with the 10 May 2005 move by the ACCC, who have advised a clamp down on the growing use of heath claims widely used to promote fruit juices, smoothes and related fruit juice products as misleading and deceptive conduct at the expense of consumers. It is worth noting that the ACCC has a definition of cosmetic in its legislation which is the same as that in the industrial chemicals legislation, while the therapeutics legislation does not include a definition of cosmetic and has no jurisdiction over this class of products.

We see NICNAS and the TGA being stakeholders along with industry but the ACCC being the responsible authority. Australia should develop a self regulatory approach, as New Zealand has done, to the responsible control of cosmetic claims and advertising.

CTFA supports Recommendation 1 that the Cosmetic Claims Guidelines be revised but with ACCC as the responsible regulatory authority.

Recommendation 2:

Antiperspirants
Antiperspirant preparations that derive their antiperspirant properties from inorganic salts (or their organic complexes) of aluminium, zinc or zirconium only should not be classified as therapeutic products under the Joint Agency. Antiperspirants other than these should be regulated as Class II medicines.

CTFA Comment:
We support this recommendation as the reclassification is consistent with that in the EU and New Zealand. It also means that ingredients used in these products will be known to consumers and come within the jurisdiction of NICNAS. They will no longer sit outside of either TGA or NICNAS assessment. We note that in both Europe and the USA zirconium salts are not permitted to be used in aerosol products. This is also the industry self regulated position in Australia and as such should be a requirement of NICNAS and perhaps controlled if necessary by an appropriate SUSDP limitation.

CTFA supports Recommendation 2 that Antiperspirants with inorganic salts of aluminium, zinc or zirconium should be treated as Excluded Goods.

Recommendation 3:

Antidandruff preparations
Antidandruff shampoos, hairdressings or lotions should be classified as therapeutic products by the Joint Agency.

If the antidandruff product is not included in any Schedule to the SUSDP,
(a) The product should be exempted from licensing; and*
(b) The premises where the product is manufactured should be exempt from licensing.

CTFA Comment:
While the recommendation to regulate these products as Therapeutic Products – Exempt is acceptable and remains unchanged from the current classification in Australia there remain some inconsistencies with this classification.

Firstly, we are not sure that an "exempt" category is planned under the Joint Agency. If market acceptance combined with a low risk profile is a criteria then there is a strong case for this category of products to become classified as Excluded Therapeutics i.e., cosmetics as in the EU. Consumers do not see mild dandruff as a medical condition but rather as evidence of uncleanliness.

All inconsistencies are easily resolved if antidandruff products particularly those using pyrithione zinc or piroctone olamine are classified as excluded therapeutics.

Separate comment is required on the situation in New Zealand where antidandruff products are classified as "related products" and require an application to be made and approved before marketing. This involves a fee of NZ$5000 and an evaluation and approval that in the past could take from 3-12 months. Transitional arrangements since 31 December 2004 have resulted in some changes and now require the same application to be made, the same fee paid, but no evaluation is made provided documents are in compliance.

It is not clear what a classification of exempt therapeutics would mean in New Zealand as this may still keep products out of the jurisdiction of ERMA and the HSNO Act.

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* If Exempt or Similar exists under the Joint Agency.

The recommended classification does not resolve the issue in Australia of how and by whom new excipients are reviewed. This was an important consideration raised during the LRCC process. CTFA believe this is best placed with NICNAS.

We therefore believe that in the best interests of both Australia and New Zealand that a classification of antidandruff products (and not just shampoos) provided they use designated antidandruff agents could be classified as cosmetics. With non designated antidandruff agents they could be controlled through the use of SUSDP scheduling and labelling conditions.

The CTFA does not fully support Recommendation 3 because we believe risk assessment supports a classification of excluded therapeutics for antidandruff products using well established unscheduled antidandruff ingredients. An exempt category as recommended does not address the assessment of ingredient safety issues or the need for full ingredient labelling.

Recommendation 4A:

Sunscreens
A. Primary sunscreens where SPF is ≥ 4 *should be classed as therapeutic products and described as Class I medicines.*

As a condition of licensing, the SPF of each product must be determined by the method prescribed by AS/NZS 2604:1998 for the particular product. The Joint Agency should consider moving to an acceptable international standard when one becomes available.

The Joint Agency Rules should specify that all performance statements and markings on the product label (both "mandatory" and "optional") are expressed in the manner prescribed by AS/NZS 2604:1998 and no other.

CTFA Comment:
CTFA accepts the classification of Primary Sunscreens as Therapeutic Products (Class I) although we believe a cosmetic classification as exists in New Zealand and in the EU could be justified.

We strongly support the recommendation that the Joint Agency move to recognise international standards for testing of sunscreens. We believe that for **static SPF** testing this situation already exists and has existed for sometime. In the USA the FDA method as described in the "Sunscreen Drug Products for Over the Counter Use Final Monograph (May 1999)" has been used for many years and is accepted universally as a reproducible and acceptable method for determining static SPF. It is likely that the number of tests done using this method is a magnitude greater than the number done by the method of the AS/NZS 2604:1998. There is also the "International Sun Protection Factor (SPF) Test Method" used in Europe, Japan and South Africa (Feb 2003) which is also recognised as an international standard for static SPF testing. The Canadian position on SPF testing methodology is interesting.

Their Monograph Sunburn Protectants states:

> *It should be noted that absolutely no attempt has been made here to describe or establish an official method. The conditions for determining an SPF depend on the product being tested, and any methodology development or modification necessary to validate claims is the manufacturer's responsibility.*

It can be therefore argued that there are international test methods already available for Static SPF testing and have been available for many years and these should be recognised and approved as alternatives to the AS/NZS2604:1998. Work on a single world or ISO sunscreen testing standard appears to be some years away and deferral to await such a standard is unwarranted. The AS/NZ standard method has not been updated for over seven years and if the guiding principles of the Review are to recognise international best practice then continued acceptance of only the AS/NZS for static SPF testing appears to be no more than a barrier to trade.

CTFA accepts Recommendation 4A but would like clarification on the points above. We believe there is no case not to recognise now the FDA and international methods for Static SPF testing as alternatives to the method of AS/NZS2604:1998.

Recommendation 4B:

B. ***Primary sunscreen products where the SPF is <4*** should not be classified as therapeutic products.

While we agree, we fail to understand what is magic about SPF<4?

CTFA Supports Recommendation 4B that primary sunscreen products where SPF is <4 should move from exempt therapeutics to be classified as excluded therapeutic products.

Recommendation 4C:

C. Moisturisers that contain a sunscreen as and for a secondary purpose where the SPF ≥4 *should not be classified as therapeutic products 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;
(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.
An Australia- or New Zealand- specific disclaimer or advisory statement to the effect that the product is only for use as a cosmetic should not be compulsory on moisturisers that are secondary sunscreens.

CTFA Comment:
We expect that you will receive much advice on this recommendation of itself and on why the limit of SPF 20 or below is unscientific. We also expect there will be those that want to have the limit lowered to 15 or even lower. We would prefer the SPF range to extend to SPF 30. All SPF 30+ products then would be listable therapeutic products that can make anti cancer claims. On balance we consider a limit of SPF 20 is not unrealistic and are prepared to work with this classification limit. We think this is a rational compromise.

We bring to your attention again the position of the Skin & Cancer Foundation that has made supportive submissions in the past to the TGA on moisturisers with SPF in 8 April 2003. Dr Margaret Stewart Chief Executive Officer and Medical Director of The Skin & Cancer Foundation Australia stated:

"All dermatologists are supportive of maximum protection sunscreens and other aids to protect individuals from the sun and to reduce skin cancer. Dermatologists also want labelling of all ingredients on packs for safety reasons. The expansion of the use of sun protective products and an increase in ingredient labelling would be both enhanced if moisturisers with SPF were classified as cosmetics".

The Skin & Cancer Foundation Australia therefore are supportive of the widest possible use of sunscreen filters in products provided there are safeguards as to the safety of formulations and their efficacy. The SPF should be as high as possible and filters should be in all moisturisers and excessive barriers should not be placed on the marketing of such products.

The Review proposes that a large number of conditions be placed on moisturisers with SPF. We agree with them all as itemised as C (a) to C (j) but wish to comment on the last two. Items C (i) and C (j) proposes a limit of 300mL on the size of the pack to be sold and while this is not a major problem, intensive care body lotions are sold for use on dry legs that are in packs of usually 200mL and 375mL.

A sunscreen in these is a useful addition. Item C (j) proposes to restrict performance claims to that detailed by AS/NZS2604 and no other. Cosmetics make a number of cosmetic performance claims including those for helping block free radicals through the use of antioxidants. If the wording in the Review specifically relates to sunscreen protection claims and no other claims it should be so stated and this will remove our concerns.

The fact remains that many products that fall into this product category are currently denied to Australian consumers, but are available in the rest of the world. They are denied because the cost and restrictions of listing as a therapeutic product make it not worthwhile to produce a unique product for a relatively small market like Australia.

This recommendation would permit more complete ranges for Australian consumers and maintain full ingredient labelling.

The body of the Review covers many elements leading to this recommendation. This is the most thoroughly discussed portion of the whole Review and the conditions contained in this recommendation are stringent. These conditions ensure that the efficacy of product performance claims are controlled but limited and consumers are better informed. The cosmetic industry accepts and will work with them.

CTFA supports Recommendation 4C because with the ten conditions attached, there is improved availability of products in the market with absolutely no diminution of safety standards. The appropriate level of regulation remains in place, consumers will be better informed and will recognise the excellent experience of similar products on the market that have already been classified as excluded goods. We accept SPF 20 as a realistic but arbitrary compromise cut off to resolve a long outstanding interface issue.

Recommendation 5:

Antibacterial skin washes

A. Antibacterial skin washes *(including antibacterial hand wipes) should be classified as therapeutic products and described as Class II medicines.*

B. *The Joint Agency, in conjunction with NICNAS, ERMA and 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;
(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.

CTFA Comment:

We find this category of products somewhat harshly reviewed with more weight on the long standing and theoretical debate about effects of bactericides on the development of resistance in bacteria than on the personal, household and hospital uses of products and the perceptions of these products by consumers.

The CTFA supports a tiered approach to this product category that will be based on the nature of the claim and the proposed use. This approach would give:

- Excluded Goods - general household/domestic anti-bacterial skin washes, medicated soaps and wipes for use on unbroken skin,
- Class I - products for commercial food, specialty and occupational areas, and
- Class II - products for hospital and surgical use.

Relevant controls for excluded skin washes, medicated soaps and wipes can be exerted via NICNAS, the ACCC, and the cosmetic claims guidelines.

CTFA does not support Recommendation B. In 1998 a FDA advisory panel determined that "antibiotic resistance due to the use of antibacterial wash products is not a public health concern." NICNAS are currently investigating Triclosan as a Priority Existing Chemical so the need for another committee to look at these issues yet again seems superfluous.

CTFA does not support Recommendation 5. We believe that a tiered system is needed with general household/domestic anti-bacterial skin washes, medicated soaps and wipes for use on unbroken skin being classified as Excluded Goods; Products for commercial food, speciality and occupational areas as Therapeutic Goods (Class I), and products for hospital and surgical use as Therapeutic Goods (Class II). We do not see the need for further investigations or committees proposed by Recommendation B.

Recommendation 6:

Antibacterial skin cleansers (anti-acne products)
Antibacterial washes that are represented to prevent or treat acne or pimples should be classified as therapeutic products and described as Class II medicines.

CTFA Comment:
We have always classified skin cleansers as cosmetics even those for acne prone skin and believe there has been some confusion in the description of this category in the Review with the real interface products being anti-acne treatment products.

There are three types of products in the market in this category. The first two types are products that have a therapeutic effect on acne, spots, zits or pimples and their active ingredients are either in the Standard for Uniform Scheduling of Drugs and Poisons or not. The other type or products are products that cleanse and have no direct therapeutic claim. Those products that claim to wash, to remove sebum or shrink pores whether for dry skin, oily skin or acne prone skin are cosmetics and should remain so.

Those products that contain an active ingredient which is not in the SUSDP could be classified as Excluded Goods in the same way as antiperspirant products have been. Alternatively they could be classified together with products that contain an active ingredient in the SUSDP and we believe this should not be Class II based on the public health and safety risk.

CTFA does not support Recommendation 6 and recommends that products containing active ingredients to support a "helps treats acne claim" could be classified as Excluded Goods. The products that make cleansing claims only are already classified as cosmetics.

Recommendation 7:

Toothpastes and mouthwashes

A. Desensitising toothpastes and gels *should be classified as therapeutic products and described as Class II medicines.*

B. Toothpastes and gels that contain 1000 mg/kg or less of fluoride ion *and that do not make any claim (except cosmetic claims) other than preventing caries or preventing or removing plaque should not be classified as therapeutic products.*

C. 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.*

D. 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.*

CTFA does not support Recommendation 7A, desensitising toothpastes and gels should be treated as Excluded Goods. CTFA supports the remaining elements of Recommendation 7 except that anti gingivitis mouthwashes should be classified as Therapeutic Goods (Class I).

Recommendation 8:

Other product categories that may be candidates for reform
Personal lubricants should be classified as therapeutic products, irrespective of any representations that are or are not made.

CTFA Comment:
Any classification of products as therapeutic products should come back to the classification of the level of risk and the purpose of the product. Personal lubricants for internal human use are classified as medical devices and should continue under this classification. Medical devices are included in the ARTG. We do not support a higher classification of medicine Class I or Class II as these are low risk products. We are unaware of significant public heath and safety adverse complaints for these products used either internally or externally.

We believe there are products that are not used internally for purposes such as massage oils or moisturisers that should not be classified as therapeutic products and should continue to be classified as cosmetics.

CTFA does not support Recommendation 8. The classification of a product should depend on risk including representation or purpose of use as made. The most appropriate classification for products making representation for internal human use would be as medical devices. Products making representation for external use should be classified as cosmetics.

The Question of G.M.P.

The CTFA and its members are concerned with the perception without justifiable evidence in the Review and covertly suggested by opponents of change that cosmetic manufacturing premises may not be hygienic and that the industry has no self imposed GMP controls

Mandatory or not, the facts are that the Australian cosmetic industry, through the CTFA developed a Code of GMP (including Microbiology requirements) in the late 1970's which was in place and used throughout the Australian industry from that time. (We also note that similar, almost word-for-word, standards were operative in New Zealand from the early eighties).

The writer of this comment on behalf of the CTFA was deeply involved in the preparation of both and can speak first hand that the reason this industry action was undertaken was to underline the industry's commitment to produce safe and effective products.

Secondly, we also believe that a corporation could be prosecuted for quality breaches under the Trade Practices Act s53 and s53 (a) which state:

> "A corporation shall not in trade or commerce, in connection with the supply or possible supply of goods or services or in connection with the promotion by any means of the supply or use of goods or services:
>
> (a) falsely represent that goods are of a particular standard, quality, value, grade, composition, style or model or have had a particular history or particular previous use."

Over the years the supply character of the industry has changed. Much supply of products today comes from Europe and America. We estimate about 75% of all cosmetic, toiletry and fragrance products are now imported. Those products are produced under EU and US requirements *and* it should be known that the global industry has embraced and has worked to guidelines developed by COLIPA in Europe and CTFA in America *for many years.* For the last four years each of these organisations has been working on a global *ISO Standard "Cosmetics –GMP-Guideline on Good Manufacturing Practice" (Draft Standard ISO/CD 22716)* which largely embraces the guidelines already established and used.

These cover *GMP for plant, equipment and procedures as well as* stability testing, microbiology and packaging and labelling standards.

The Draft Standard ISO/CD 22716 is supported by all the countries of the EU, USA, Japan, ASEAN countries and South Africa. It is expected it may also apply to Australia and New Zealand. .

The bottom line is that the industry has shown itself to be responsible even when not legislated to be so. The level of product performance and safety that now exists is because there is acknowledgement of the responsibility by the person placing the product on the market, rather than being regulated by a prescriptive system.

We remain disappointed that the commitment the cosmetic industry has to protection of human health by producing safe products was not recognised in the Review. We sincerely hope that the responsible nature of the cosmetics industry towards quality is now recognised. Quality is not only a market imperative in the modern world, for our industry it is a way of life. The industry is committed to keeping it that way but wants to do so in a manner that avoids unnecessary administrative burdens.

Conclusion

Thank you for considering our comments. We hope that you will move quickly to implement the Review recommendations in regard to moisturisers that contain a sunscreen as and for a secondary purpose where the SPF ≥4.

This recommendation and a number of other recommendations can be implemented now without waiting for the establishment of the Joint Agency. CTFA would support this occurring.

Additionally, we recommend that regulating the Interface products, through the ingredients they contain with full ingredient labelling through NICNAS and the ACCC would be much more efficient for both the regulator and industry with no loss of safety. Consumers would be better informed and have wider choice and as a result Australia would be more in harmony with world practice.

We are willing, if need be, to work further and with continued consultation on the potentially contentious issues of regulatory classifications.

CTFA thinks that all the comments we have made can be resolved with goodwill within the principles established for the Interface Review. CTFA will be happy to work with you on any transition issues that develop as this process moves forward.

Yours Sincerely

John M. Woods
Executive Director
For and on behalf of the Board of the
Cosmetic, Toiletry and Fragrance Association of Australia, Inc.

Enc. List of CTFA Members

CTFA MEMBERS

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