

Document Type	Letter		
Date Published	2005-05-18	Availability	Private
Dept/Grp/Project ID	Standards Australia Submission to TGA Review of the regulation of products at the interface between cosmetics and therapeutic goods		
Dept/Grp/Project Name	Sunscreens & cosmetics		

20 May 2005

**TGA Review of the regulation of products at the interface between cosmetics and therapeutic goods: Submission by Standards Australia**

Standards Australia wishes to offer comments on the following sections of the Discussion paper:

**Sun Protection Factor (SPF) Clarified**

AS/NZS 2604:1998 Sunscreen products – Evaluation and classification, defines the SPF as the ratio of ultraviolet (UV) radiation dose that is required to produce a recognisable constant response on skin treated with a sunscreen product compared to that required for untreated skin.

Sunburn signifies that a tolerance threshold has been reached. Sunburn is where the cumulative UV dose has damaged the skin and provoked repair and recovery processes. Sunscreens are not sun blockers; they are filters which prevent varying amounts of sunburning radiation from reaching the skin, but do not stop all the radiation from getting through to the skin. Skin damage is a function of exposure over time and if skin is exposed for long enough will burn. The length of exposure to sunlight that will result in minimum sunburn will vary from person to person.

The meaning of the SPF number, which provides information to the consumer about different sunscreens is easily explained by using the example of unprotected skin which shows a minimum sunburn after 10 minutes exposure to sunlight. If it takes approximately 10 minutes for that unprotected skin to receive a minimum sunburning dose, then the same skin with an SPF 15 sunscreen will take approximately 15 times as long to they receive the same sunburning dose i.e. 150 minutes, therefore a sunscreen with an SFP of 2 to 4 does not have less sun protection properties than a SPF 15 sunscreen it just provides protection for 20 to 40 minutes instead of 150 minutes.

Therefore the claim on page vii of the report that sunscreens with a SPF of less than 4 can not be regarded as having realistic and meaningful sun-screening properties and this being provided as the reason why they should be classified as cosmetics is not based on scientific reasoning.

**What are the issues in relation to regulatory harmonization and the Standardization perspective?**

Page 15 of the report rightly points out that there are many barriers to both trade and regulatory harmonization. *Standardization Guide SG-007-1 - Adoption of International Standards* states "Standards Australia is to base Australian Standards on International Standards to the maximum extent feasible and to use the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (commonly referred to as the TBT Code) as a benchmark to facilitate the reduction of technical barriers to trade.

*Notwithstanding the fact that the WTO TBT Code is addressed to national governments and is only binding for technical regulations for tradeable goods, the policy extends to ensuring that all Australian Standards meet the provisions of Articles 2.2 and 2.4 of the WTO TBT Code, 1994. The immediate consequence is that Australian Standards should be adoptions of International Standards, unless there are good reasons to the contrary. This compliance would also ensure that obligations of Australia under WTO would be met if any such Standard were adopted by a government agency as a technical regulation (see Paragraph 4 of this Guide)."*

As such the review of the regulatory framework for therapeutic and cosmetic goods requires particular care with respect to sunscreen products.

SG-007-1 goes on to state *"Standards Australia is committed to complying with the elements of the TBT Code which are specifically addressed to the development process of voluntary national Standards. Annex 3 to WTO TBT Code is the Code of Good Practice for the Preparation, Adoption and Application of Standards and it is applicable to non-government standardizing bodies such as Standards Australia.*

*GATT is the General Agreement on Tariffs and Trade which Australia first signed in early 1992. The GATT developed TBT Code is now administered by the World Trade Organization. In relation to Standards, the GATT, now WTO TBT Code obliges signatory countries not to raise non-tariff (i.e. technical) barriers to trade.*

*The mechanism by which this section of the TBT Code operates is that any mandatory Standard issued by a signatory nation that might have an impact on trade must be reported to the other WTO signatories via a network of national notification points. The other nations then have a period during which they may lodge a challenge to the implementation of the Standard on the grounds that it represents a non-tariff barrier to trade. Alignment of the national Standard in question with the equivalent International standard is recognized as a full and adequate discharge of a nation's obligations under this section of the TBT Code"*

Currently there is no international committee dealing with standardization of sunscreen requirements and test methods. AS/NZS 2604 was one of the first standards developed for sunscreens with Australia considered a leader in this field in terms of standardization. It has only been recently that the European standardization bodies have published a similar standard.

SG-007-1 goes on to state *"In Australia, the Department of Foreign Affairs and Trade is the WTO Notification Point. Under Articles 2.2 and 2.4 of the TBT Code, mandatory national Standards shall not be more trade restrictive than necessary to fulfil a legitimate objective, taking into account the risks non-fulfilment would create. Such legitimate objectives include:*

- a) National security requirements.*
- b) Prevention of deceptive practices.*
- c) Protection of human health or safety, animal or plant life or health, or the environment.*
- d) Fundamental climatic or other geographical factors. Reciprocal rights of appeal under the WTO Code are available to Australian manufacturers supplying overseas markets"*

Please note that products such as sunscreens which come under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). SPS under Article 3.1 and 3.2 deems the following:

*3.1 To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.*

*3.3 Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.(2) Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement. (ref [http://www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm))*

Although standardization and international harmonization underpins the objectives and work of Standards Australia it is important to note that the expectations of the local community and consumer must also be taken into account. Items c and d above must be considered when looking at harmonization and international standardization.

For instance page 55 of the report states "*Sun protection is to be taken more seriously in Australia than anywhere else in the world because a coastal-dwelling, predominantly European population inhabits a country with ample sunshine and more and better accessible beaches than most. There is also the hole in the ozone layer that reduces protection*". Australians love of the water also contributes to further exposure to indirect UV radiation; AS/NZS 2604:1998 states, "*Substantial amounts of UV radiation can be reflected from items in the environment such as snow (up to 85%), water (up to 30%).....*" coupled with the highest rate of skin cancer in the world it highlights Australian requirements for protection from sun damage to be as high a standard as possible.

The work of Lindenschmidt *et al*/mentioned in the report points out that the practice of treating borderline products, such as moisturising sunscreens, as drugs adopted by nations such as USA, Canada and Australia does not present insurmountable barriers to harmonization. Page 58 of the report also maintains that Australia should not apologise for the stand that it has taken in terms of the more stringent regulatory control framework "*.....because of the short term and long term health problems arising from the country's climate, demographics and beach culture.....*". Standards Australia supports this assertion.

#### **International Standardization Process**

The Recommendations under Section 4 (page x) in the report states that the SPF of each product is to be determined by the method prescribed by AS/NZS 2604:1998 and that the joint Agency should consider moving to an acceptable international standard when one becomes available. Page 58 of the report also discusses the availability of international standards other than AS/NZS 2604:1998.

Currently there is an old International Commission On Illumination (CIE) standard for Sunscreen Testing for UV.B (CIE 90-1991) it reflects old technology and thinking and does not account for the growing concern UV.A testing. If an International Standard were to be developed, a proposal would need to be put forward to CIE or ISO who would in all likelihood refer the proposal to CIE which is recognised by ISO as a standardization body under the WTO agreement.

As mentioned previously, Australia has for some years been the leader in standardizing sunscreens with other nations closely monitoring or looking at adopting this standard. The Australian Committee CS-046 Sunscreen Agents is constituted according to an internationally recognised policy with a memoranda of understanding with the Federal Government recognising that Standards Australia is the nations peak standards writing body and that it represents Australia at the international level with such organisations and ISO, CIE and IEC.

CS-046 has developed a standard that sets out minimum requirements for the evaluation and classification of sunscreen products. The Committee constitution is balanced to ensure that all major stakeholders from manufacturers, testers, consumers, and health departments to regulators are represented to ensure that the developed standard has taken into account all stakeholder concerns and constraints.

Although we appreciate that the review does not attempt to disregard the Australian standard it appears to be opening the door to an "acceptable" international standard that is not recognised under the WTO agreement.

The report suggests that guidelines to be published by COLIPA (a coalition of manufacturers) will be recognised by regulatory authorities within Australia as an international standard, however COLIPA is not recognised by ISO under the WTO as an international standardization body.

#### **The Consumer**

Page 5 of AS/NZS 2604:1998 which reflects the views and decisions of the national technical standards committee points out that "*The Sun Protection Factor (SPF) informs consumers of the efficacy of the sunscreen against*

*sunburn and helps them select a product appropriate to their skin sensitivity and exposure to the sun* clearly the average consumer associates SPF with sun protection.

Page 16 of the report points out that the average consumer makes the distinction between a drug and a cosmetic based on the presentation of goods, how they are described and the marketing that will be used to advertise the product.

Allowing moisturisers that contain sunscreens as and for a secondary purpose where the  $SPF \geq 4$  to be classified as a cosmetic even with the provisions in place has the potential to mislead consumers into the belief that the product they are purchasing meets and fulfils the same requirements as those products determined to be primary sunscreens when this is clearly not the case.

Yours sincerely,

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