Solving Sunscreen

From theory to practice: A thought starter
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Introduction

The sunscreen sector is facing challenges on multiple fronts.

Recent evidence suggests that there is a mismatch between the current sunscreen testing error margins (Cole et al. 2025) and the labelling requirement mandated in regulation. This may partially account for the CHOICE testing results we have seen in 2025 and in years before. There are new internationally approved sunscreen test methods, that appear to provide less variable results, that are not yet recognised in Australian regulations. Even more test methods are in development internationally.

Safety of some sunscreen actives are in question, and the Australian regulator is actively considering a proposal to limit some UV filters that could remove 50-75% of all existing products from Australia. At the same time, it is more difficult now than ever to gain regulatory approvals for new ingredients for use in sunscreens, making it difficult, slow and costly to replace existing products.

On top of this, recent Australian research findings show that consumers do not really understand sunscreen labels (Nicholson et al. 2025) and some of this is due to conflicting information.

Australian Sunscreen regulations and our public health campaigns must evolve to address these challenges.

Sunscreen in Australia: a roadmap to more effective & efficient regulation (the Sunscreen Roadmap) was commissioned by Accord to explore these concerns and to map a better path forward. It will be used to start a discussion with the TGA and other stakeholders.

Until these solutions are agreed and implemented, there will continue to be a gap between regulatory requirements and reality. This document is intended as a thought starter to navigate the known mismatch between regulation and reality until they are aligned so that supply of sunscreens in Australia can continue, and consumer confidence in both sunscreens and the regulatory system is maintained.

To this end, this document explores:

- **Communication and education** to assist consumers select the right product,
- **Differentiating between regulatory flags** to identify those that point to real problems, and
- **Preparing for changes ahead**.

Communication and education

Before we can identify the best way to communicate with consumers, we must first understand what it is that we want to communicate and where there may be a mismatch and confusion.

Below is a brief explanation of sunscreen testing and labelling, recent developments and how other regions are addressing challenges.

Explanation of sunscreen testing and labelling

SPF claim

Efficacy testing of sunscreens products, or sun protection factor (SPF) relies on testing of 10 human subjects, where the sunscreen is applied by a human, and after UV exposure, observation of the 'redness' of the skin made by a human to determine the SPF of the tested product[1].

With human subjects and human judgement, it has long been hypothesised that there may be significant variability in SPF test results.

To improve the existing SPF test method and remove variability, the Double Plate Method (DPM)[2] and the Hybrid Diffuse Reflectance Spectroscopy (HDRS)[3] were developed and approved as official International Standard Organisation (ISO) test methods in December 2024. Australia is currently in the process of considering allowing these methods for placing our sunscreen products on the market. There is also more work on the way internationally to validate *in vitro* and hybrid methods for water resistance. Until the ISO methods are recognised in regulation, they can be used to support *in vivo* SPF test but cannot be relied upon for regulatory compliance.

Recent studies, including Cole et al. (2025) into the extent of variability in *in vivo* SPF test results show seemingly increasing variability or error margins at high SPF. However, if we consider the error margin as a function of the amount of UV light (rather than the SPF number), then the error margin is relatively uniform across all test results.

This is due to the SPF being a measure in log scale. This means that as SPF number increases, the additional amount of UV light filtered out relative to the increasing SPF number reduces rapidly:

- SPF 8 = 85% UV filtered
- SPF 15 = 93% UV filtered
- SPF 30 = 97% UV filtered
- SPF 50 = 98% UV filtered
- SPF 100 = 99% UV filtered

If we assume a 1% error margin for UV light in an *in vivo* SPF test, a high SPF product e.g. SPF 50 (98% UV) can test anywhere between SPF 30 (97% UV) and SPF 100 (99% UV). For a moderate SPF product, e.g. SPF 15 (93% UV), the same error margin of 1% would produce results between SPF 12 (92% UV) and SPF 18 (94% UV).

Based on this information, it is evident that the SPF label mandated by current regulations, through the adoption of the Australian Sunscreen Standard, AS/NZS 2604:2021[4], is likely to result in mislabelling products for high SPF sunscreens. Relevant parts of Table 1 from AS/NZS 2604:2021 is replicated below.

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[1] The full *in vivo* SPF test method is detailed in ISO 24444:2019
[2] The *in vitro* SPF test method detailed in ISO 23675:2024
[3] The hybrid (using both *in vivo* and *in vitro*) SPF test method detailed in ISO 23698:2024
[4] Australia is currently in transition from AS/NZS 2604:2012 to AS/NZS 2604:2021

SPF	Labelled SPF	Category description
4 - 14	**4, 6, 8, 10**	Low protection
15 - 29	**15, 20, 25**	Medium/Moderate protection
30 - 59	**30, 40, 50**	High protection
60	**50+**	Very high protection

Internationally this point is recognised. The international industry, particularly the EU, has been working to not only reduce the error margin through improved test methods, but also to improve consumer communication. There is an active discussion in the EU to increase the focus on category description and reduce the focus on the SPF number on the label.

Water resistance claim

To claim water resistance for sunscreens in Australia, a product must undergo a 'post-emersion' test. This is where sunscreen is applied to the test subjects, then the subjects are 'emersed' in water for a set duration (40 minutes, 2 hours or 4 hours) before UV exposure and assessment of redness of the skin to determine the SPF of the product. The maximum water resistance claimed is also linked to the SPF of the product e.g. products with SPF <30 cannot claim water resistance of 4 hours (AS/NZS 2604:2021).

This process is different to most other parts of the world where water resistance can be claimed if <50% of the sunscreen product is washed off in a given timeframe.

Reapplication statement

Regardless of the test method used, SPF of the water-resistant product and duration of water resistance, a consistent public health messaging is that all sunscreens should be reapplied frequently, and at least every two hours.

While it is a requirement in the USA to label sunscreen products with 'reapply every two hours' (U.S. Food and Drug Administration 2021), it is technically not a legal requirement in Australia.

Our requirements are seemingly more flexible with a requirement to label the product with *"apply generously to the skin 20 minutes before skin exposure, then reapply frequently, and after swimming, sweating or towelling" or words to the effect* (AS/NZS 2604:2021, p.6). However, we also have a requirement that advertising (which includes on label) should not be inconsistent with current public health campaigns (*Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021*).

This leads to rather confusing messaging for products that are 4-hour water resistant that they too should be reapplied at least every two hours.

Similarly for a relatively new sunscreen category 'face sunscreens', the mandatory statement to reapply after swimming, sweating or towelling is incongruous with its use.

A way forward

There is a need to change the way we communicate with the Australian public so that they can make informed choices that suit their needs.

While some changes to regulation is needed, there is also a need to separately consider our public health messaging. The regulation and public health messaging must also move in the same direction.

We should also consider how we can convey the importance of sun protection while acknowledging the benefits of some sun exposure for a proportion of the population. The position statement *Balancing the harms and benefits of sun exposure* (Neale et al. 2024) that came out of the Sun Exposure Summit in March 2021 is an example of such consideration. This would support consumers make informed choices based on their own personal needs and help address any misinformation that proliferates through social media.

One option to consider, following the discussion in the EU, is to increase the focus on sunscreen product category (low, medium, high and very high protection), and encouraging selection based on categories rather than SPF numbers. Currently AS/NZS 2604:2021 mandates prominent SPF number labelling on sunscreen products. The category description is not mandated but allowed.

Differentiating between regulatory flags

The CHOICE publication of its testing in 2025 of some sunscreen products brought into sharp public focus the variability of SPF testing. We will need to wait for the TGA to finalise its investigation to fully understand the issues that underpin the test results.

However, there is a mismatch between current regulatory requirement for labelling of products, requirement for validation when re-testing, and expectations of all parties that appears to be confusing matters. This needs to be clarified so that compliance focus can be on products with real problems.

Current regulatory guidance

Determining the label SPF

According to AS/NZS 2604:2021, a product that returns a SPF result between 50 or 59 inclusive must be labelled as SPF 50. This can be done after a single valid SPF test of the product.

Validation of SPF of a product

According to *Understanding the Regulation of Therapeutic Sunscreens*:

> *Subsequent retesting of a sunscreen is likely to yield a mean SPF anywhere within the 95% CI from the original testing of the product or even a few SPF units beyond either end of that 95% CI.* (Therapeutic Goods Administration 2025, p.30)

Compliance prioritisation

Determining the 95% confidence interval

There is no regulatory guidance on how to determine the 95% confidence interval of a labelled SPF. It is possible that the 95% confidence interval depends on the type of formulation or perhaps even individual formulations. Companies that have long history of developing and testing sunscreen products may have determined the 95% confidence interval for their products.

However, where the 95% confidence interval is not readily available for a product, Cole et al. (2025) provides a '95% predictive interval' that may be useful.

According to Cole et al (2025, Figure 5), the upper limit of the 95% predictive interval for a given SPF number can be calculated using the formula y=1.7191x and the lower limit can be calculated using the formula y=0.5817x, where x is the 'true' SPF. Using this formula, a SPF result anywhere between 29 and 85 is within the 95% predictive interval for a SPF 50 sunscreen.

Products that fall outside the 95% confidence interval – higher priority

The 95% confidence interval that is much broader than the specified SPF label range means that using a single *in vivo* SPF test to determine the product label SPF will inevitably lead to mislabelling of some sunscreen products.

A 95% confidence interval of SPF 29 and SPF 85 for a product with SPF 50 also means that a product that returns a test result of SPF 50 may have a 'true' SPF anywhere between 29[5] and 85[6].

Clearly regulatory change is needed to remedy this.

Until then, a measured approach is needed to address this issue – statistically, approximately 35% of products may fall below the 95% confidence interval, even when all regulatory protocols have been followed.

Challenges to compliance investigations

Australian regulatory requirements for sunscreen testing puts the onus on ensuring the validity of the test on the Sponsor of the product.

Sunscreen testing is a niche service offering. Globally there are only a couple of dozen sunscreen testing laboratories. There is no requirement for these laboratories to be accredited to any particular standard, with different laboratories leveraging various good laboratory practice and quality management systems.

When there is a spike in testing numbers, which can occur around any type of transition e.g. ingredient phase out, regulatory changes, etc., there is often a backlog of SPF tests and Sponsors may be using new laboratories that they may not have used previously. Each Sponsor has their own supplier onboarding system.

[5] using the equation x=50/1.7191, where SPF 50 is the upper limit of the 95% predictive interval
[6] using the equation x= 50/0.5817, where SPF 50 is the lower limit of the 95% predictive interval

Australia is currently in transition from AS/NZS 2604:2012 to AS/NZS 2604:2021, with the transition ending in mid-2029. All products that are currently on the market must either be re-tested to the newer standard or be phased out. There are approximately 1000 sunscreen products that are currently regulated by the TGA, and it is estimated that there are three times as many cosmetic sunscreens on the market[7].

The cost of *in vivo* SPF testing is in the ballpark of $10 000. *In vitro* SPF test which may cost a fraction of the *in vivo* test (in the ballpark of $1 000) can be used to support existing in vivo test that meets regulatory requirement – but these tests are still new, and the extent of variability across the different methods (*in vivo*, *in vitro* and hybrid) and across different types of sunscreen formulations is yet unknown.

Further, there is no magic number of tests that can provide the 'true' SPF of a product. Statistically, it is possible for a number of consecutive tests to return an SPF result that is close to the upper limit of the 95% confidence interval only for one further test to return a result that is close to the lower limit of the 95% confidence interval and vice versa.

Adding to this concern, there is a lack of clarity on the future of key sunscreen actives in Australia that are currently used in approximately 75% of all TGA regulated sunscreens, and the need for Sponsors to start all over again if most of their products need reformulation.

To address some of these challenges, the TGA has published *Advice for sunscreen sponsors and manufacturers: Acceptance of additional SPF testing information* (Therapeutic Goods Administration 2025) on its website. It should be noted that this is an interim advice.

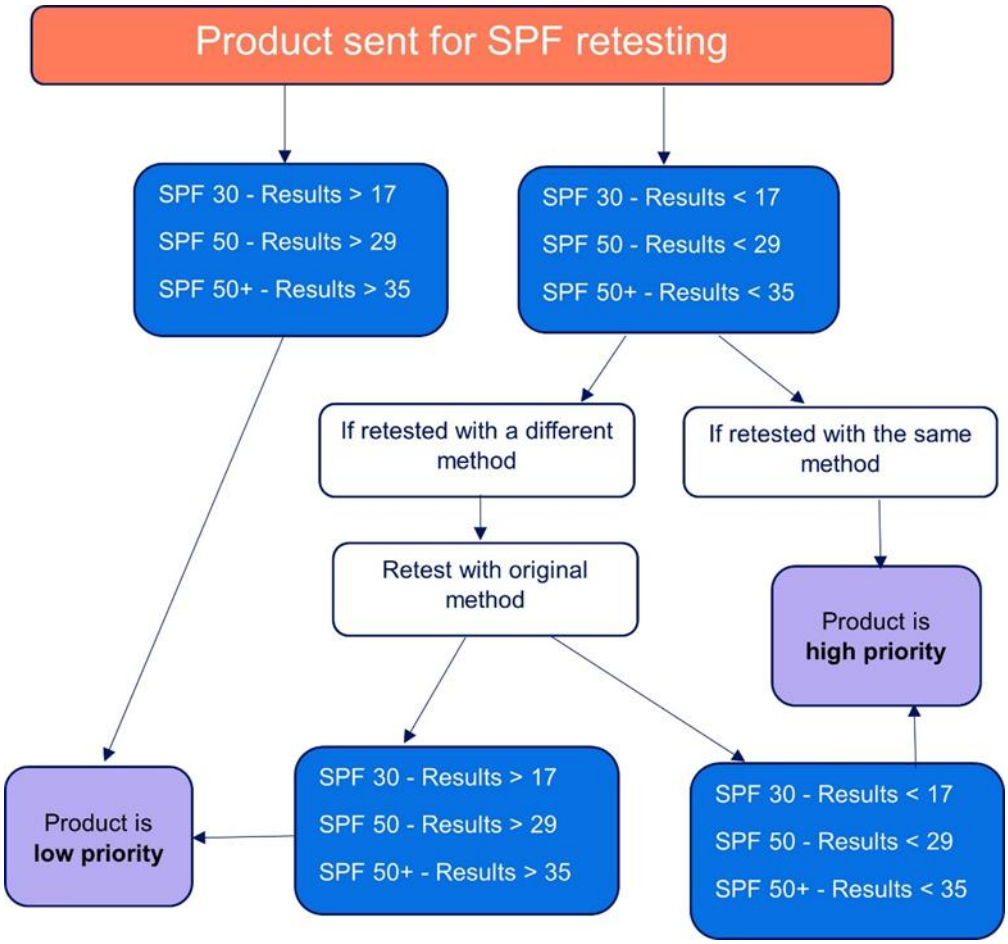
Accord has put together a summary of sunscreen testing laboratories, what they offer and their accreditation. This is provided as Appendix 1.

Further work is required to work through all challenges. However, the focus for now should be firmly on the higher priority products.

Graph 1 summarises the prioritisation process.

[7] cosmetic sunscreens must also meet the same efficacy testing requirement, and transition from the old to new standard

Graph 1



Note: A weight of evidence approach and expert judgement should be used to determine whether a product meets the SPF claimed on the product label. This requires careful consideration of all evidence at hand, and a clear picture may only emerge after multiple re-tests.
Some of the factors to consider are:

- Current regulatory requirements
- The SPF test method used
- Whether the test was an 'indicative' test using a reduced panel or a full panel test
- Any potential concerns with the laboratory that conducted the test
- The full range of SPF endpoints from all relevant tests, with potentially variable weights to their usefulness

Preparing for changes ahead

The sunscreen sector is facing challenges on multiple fronts. How we address these challenges will have a lasting impact on public health, Australian skin cancer rates, and the health of the local sunscreen industry.

We need a step-wise approach – a project plan – to address these challenges one at a time.

It is no use re-testing every sunscreen product on the market to verify the SPF of all products, if we don't know whether those products can continue to be marketed after the review of some sunscreen actives.

We should not be removing 50-75% of all sunscreen products from the market if our formulators cannot access to the same ingredients available overseas and TGA cannot approve ingredients fast enough and at a reasonable cost to allow our formulators to reformulate effective products to replace them. There are hundreds of ingredients that are in use in sunscreen products overseas and cosmetic products locally that cannot be used in Australian sunscreens.

We also need to engage with international developments in SPF testing, evolving labelling and other communication challenges, and review and development of new ingredients so that we stay relevant and competitive in the global market.

We have some of the best sunscreen innovators in the world in Australia that have firsthand experience and understanding of the need for sun protection. The challenges we face could be an opportunity for Australia to once again be a leader in sun protection products – but only if we seize the opportunity.

Appendix 1

Sunscreen Efficacay Testing Laboratories

Version 2, Updated 17 October 2025

Testing Faculity	Location	Accreditation				Test methods offered							Contact	Website
		AS ISO/IEC 17025	Good Laboratory Practice certification	ISO 9001 accreditation	Other	ISO 24444	ISO 24443	ISO 16217	ISO 18861	ISO 23675	ISO 24442	ISO 23698		
		Scope				SPF (In Vivo)	Broad Spectrum (In Vitro)	Water resistance (In Vivo)	Water resistance	SPF (In Vitro)	UVA (In Vivo)	Hybrid Diffuse Reflectance SPF (In Vitro)		
Advanced Science Laboratories	New York, USA		GCP Compliance	X	BIPEA FDA Registration	X	X	X	X				Marcin Skolik Office: +1-845-638-0309 Cell: +1-845-671-9192 marcins@advancedsl.com	www.advancedsl.com
ALS Global	Brazil	UVA			BIPEA FDA Registration	X	X	X	X	X	X (Nov)	X	Felipe Spinelli Felipe.Spinelli@ALSGlobal.com	https://www.alsglobal.com/en/claim-substantiation/sunscreen-and-uv-protection
Eurofins Cosmetics and Personal Care	Spain			X		X		X	X				Maria Torrego maria.torrego@cpt.eurofinseu.com	https://www.eurofins.com/
Eurofins CRL	North Carolina, USA		Follow GCP Guidelines	X		X	X	X			X		Chelcie Mejia Chelcie.mejia@cpt.eurofinsus.com Yvette Gonzalez Yvette.gonzalez@cpt.eurofinsus.com	https://www.eurofins.com/
Eurofins Dermatest	NSW, Australia			X	BIPEA	X	X	X	X	X	X (Dec)		Craig Dennyson Craig.Dennyson@eurofinsanz.com	https://www.eurofins.com/cosmetics/products/sun-care/
Eurofins Dermscan	France		GCP-ICH Audits	X		X		X	X		X	X	dg_cfr242_photobiology.project.manager@cpt.eurofinseu.com Anne.Bouet@cpt.eurofinseu.com	https://www.eurofins.com/
Eurofins Dermscan	Gdańsk, Poland		GCP-ICH Audits	X	BIPEA	X	X	X		X	X		Solar@cpt.eurofinseu.com anna.ludwikowska@cpt.eurofinseu.com	https://www.eurofins.com/
Florida Skincare Testing	Florida, USA		GCP compliant		FDA Registeration	X		X					Tia Rush clientservices@flskincaretesting.com	https://www.flskincaretesting.com/
GBA Group (GBA Cosmetics)	Poland	Scope in polish				X	X	X	X	X	X		Simon Putnam s.putnam@gba-group.de	https://www.gba-polska.pl/en/
Normec Schrader Institute	Holzminden & Kassel, Germany			X		X	X	X	X	X	X	X	Sai Panguluri Project Manager – Sales & Communication +49 5531 9313410 +49 151 20645073 Sai.Panguluri@normecgroup.com	https://schrader-institute.de/en/knowledge/sun-protection/
Dermatest	Muenster, Germany			X			X			X		X	Dr. Katja Adames Senior Study Manager Epicutaneous Testing dr.adames@dermatest.com	https://dermatest.com/
Weneos	France			X	BIPEA FDA Registration		X			X		X	Guillaume LEJEUNE glejeune@weneos.com commercial@weneos.com	https://weneos.com

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