

Factors Affecting SPF Accuracy in Sunscreens and Recommendations for Regulatory Reform

An Aesthetic & Beauty Industry Council Report

DRAFT FOR INDUSTRY REVIEW

By Stefanie Milla CEO | Director ABIC

Introduction

Australia has one of the highest skin cancer rates in the world, so confidence in sunscreen efficacy is paramount. Recent findings by consumer groups (e.g. CHOICE) that many sunscreens failed to reach their labelled SPF have raised concerns. It is a longstanding and widely known issue among skincare and sunscreen formulators that multiple scientific, regulatory, and formulation factors can cause a sunscreen's actual protection to fall short of its claim. This report examines those factors in depth and compares how different regions address SPF compliance. We also evaluate Australia's current compliance monitoring system and propose reforms. This report explores the key issues, from formulation stability and ingredient interactions to testing methodologies and regulatory oversight – followed by practical recommendations. The goal is to provide skincare brands and regulators with a framework to restore and maintain consumer trust in sunscreen labelling.

Key Factors Affecting SPF Performance

Even when a sunscreen is formulated to meet a target SPF in the lab, several variables can erode its effectiveness by the time it reaches consumers:

- **Formulation Composition & Stability:** The product must contain the correct concentration of UV filters evenly distributed. If a formulation doesn't actually have the intended amount of active ingredients or if those actives aren't uniformly dispersed, the SPF will suffer. Stability is critical, emulsions that separate or actives that precipitate out will create "hot spots" of low protection. Formulators design emulsifiers and thickeners to keep ingredients well-mixed over the product's life. They also conduct accelerated stability tests (e.g. storing at elevated temperatures) to ensure the SPF remains consistent up to the expiration date. If a sunscreen is not stable for at least 3 years, Australian regulations require an earlier expiry date on the label to reflect its shorter shelf life.
- **UV Filter Photostability & Interactions:** Some UV filters can degrade upon exposure to sunlight (UV radiation), reducing protection over time. For example, the common UVA filter avobenzene (butyl methoxydibenzoylmethane) is known to be photounstable on its own, its efficacy drops as it breaks down under UV. Formulators counter this by pairing it with stabilisers like octocrylene or certain antioxidants, which significantly improve avobenzene's photostability. Conversely, certain ingredient combinations can undermine each other. A classic case is avobenzene and octinoxate: avobenzene can hasten the photodegradation of octinoxate, meaning a formula containing both needs careful design or additional stabilisers. Inorganic filters (zinc oxide, titanium dioxide) are intrinsically photostable, but if they are not properly coated, they can act as photocatalysts that generate reactive species and degrade nearby organic ingredients. A formulator must balance the UV filters used, ensuring they complement rather than compromise each other.

- Degradation Over Time (Heat, Light, Oxygen):** A sunscreen’s environment during storage and use can drastically affect its SPF. Heat can accelerate chemical breakdown, for instance, high temperatures in a car or on the beach may cause filter molecules to denature or preservatives to fail. UV light exposure can start degrading the product while still in the container (especially if the packaging isn’t fully opaque). Even oxygen seeping into the container can oxidize sensitive ingredients over months. These factors mean an SPF50 product made with photounstable filters might drift below SPF50 as it ages, unless formulated and packaged to prevent it. Tests have shown some filters lose effectiveness with prolonged UV exposure, e.g. certain cinnamate and camphor derivatives retain only a portion of their protective power after absorbing UV, with the rest of the energy causing chemical changes. If a formula doesn’t include stabilisers to quench these reactions, its protection can diminish before the user even applies it.
- Packaging and Shelf-Life:** Packaging is the formulator’s first line of defense to preserve efficacy. Sunscreen packaging needs to protect the product from light and air. For example, UV-blocking tubes or dark tinted bottles can prevent retail lighting and sunlight from penetrating and degrading the filters. An effective package also limits air exposure; many modern sunscreens use air-tight pumps or tubes to reduce oxidation. Good packaging can also mitigate temperature swings (some materials have insulating properties). However, there is a current push for sustainable packaging, and recyclables or biodegradable materials sometimes have poorer barrier properties. This poses a challenge: eco-friendly packaging must still safeguard the formula’s integrity. Formulators are actively researching advanced coatings and oxygen scavengers in packaging to reconcile sustainability with product protection. Ultimately, even the best formula can fail to meet its SPF claim if the packaging allows degradation. That’s why stability testing includes packaging compatibility, products are stored in their actual container and stressed (heat, light, etc.) to confirm the SPF doesn’t drop below the claim by the end of shelf life.
- Application and User Factors:** (While not a formulation factor per se, it bears mentioning.) If a sunscreen’s directions for use are unrealistic or unclear, consumers may under-apply, leading to much lower protection than labelled. For instance, if the texture is greasy or leaves a white cast, users might apply too sparingly. The SPF test applies product at 2 mg/cm²; in reality many people apply far less. This is one reason a sunscreen might “not meet its claim” in practice even if the formulation is sound. User education is key: no sunscreen will work if not applied liberally and reapplied often. From a formulator’s view, making a pleasant, non-whitening formula improves compliance and real-world protection. In summary, a labelled SPF assumes ideal application, any factor that causes people to use less (poor aesthetics, confusing instructions) effectively reduces the protection they get.

(In summary, formulators must ensure a robust product: one that contains sufficient active ingredients, maintains stability under various conditions, uses synergistic ingredient combinations, and is packaged to preserve efficacy. Any weakness in these areas can result in a sunscreen that tests or performs below its claimed SPF.)

Human SPF Testing vs. In Vitro Methods

In Vivo (Human) Testing: The globally accepted standard for determining a sunscreen’s SPF is an in vivo test on human volunteers. The protocol (such as ISO 24444 or FDA’s equivalent) involves applying the product to panelists’ skin in a controlled amount, then exposing those areas and adjacent unprotected skin to UV light to find the minimal dose that produces redness (MED). The SPF

is essentially how much more UV dose protected skin can tolerate before burning, compared to unprotected skin. While this real-skin method is considered the most direct measure of protection, it comes with significant variability and subjectivity. Individuals have different skin responses, and even subtle differences in technique between labs (how the product is spread, the calibration of the solar simulator lamp, etc.) can lead to different SPF results. Indeed, the TGA notes that testing on humans “can be highly subjective” and results “differ dramatically from one individual to another,” contributing to inter-lab variability. Studies confirm that SPF values from one lab often don’t perfectly reproduce in another; a product might test as SPF60 in one laboratory and SPF50 in another, purely due to normal variation. This variability is problematic for reproducibility, a sunscreen could technically meet the required SPF in one test but “fail” in another test without any change in the formula. International regulators mitigate this by requiring statistical confidence intervals and in some cases multiple panels, but the issue remains that in vivo SPF has an inherent uncertainty range.

In Vitro (Laboratory) Methods: To address consistency and ethical concerns, Australia has adopted validated in vitro methods (no human subjects) for both SPF and UVA testing, as required by AS/NZS 2604:2021. In vitro SPF testing typically involves applying the sunscreen to a substrate (such as polymethyl methacrylate plates) and measuring UV transmission or absorbance with specialised instruments. There are well-established in vitro methods for UVA protection (e.g. the ISO 24443 test and critical wavelength determination) used to support broad-spectrum claims. While Australia accepts in vitro testing for SPF determination, a universally standardised in vitro method for UVB protection is still under refinement internationally.

Researchers have proposed predictive models using spectral absorbance and mathematical algorithms, and a new ISO in vitro SPF method is under development. The TGA acknowledges that although Australia uses in vitro methods for regulatory purposes, these approaches are still being improved to ensure closer correlation with real skin performance. In vitro methods offer advantages such as improved consistency, avoidance of human testing, and the potential for more frequent batch verification. However, limitations remain in accurately replicating how sunscreens behave on skin, particularly in relation to film formation, ingredient interaction, and photodegradation.

Reproducibility and Regulatory Challenges: The variability in human testing has real-world implications, as seen in recent controversies where a sunscreen’s in-house test said “SPF50+” but a third-party test found a much lower SPF. This has prompted calls for more robust testing requirements and possibly the incorporation of multiple test runs or lab comparisons before a product is marketed. A prudent approach for companies is to formulate with a buffer, for example, aiming for an SPF60+ in development if the label claim will be SPF50, to account for test variability. Likewise, regulators in some regions build in safety margins: the EU and Australian standards only allow an “SPF50+” label if the measured SPF is ≥ 60 on average. These margins help, but they don’t completely eliminate discrepancies in testing. In summary, improving test consistency is an active area of research.

TGA Requirements for SPF Testing and the Role of In Vitro vs In Vivo Methods

In Australia, sunscreen products are regulated as either therapeutic goods (primary sunscreens) or cosmetic products (secondary sunscreens), depending on their claims and intended use. For all primary sunscreens, which are regulated by the Therapeutic Goods Administration (TGA), compliance with the Australian/New Zealand Standard AS/NZS 2604:2021 is mandatory.

AS/NZS 2604:2021 outlines the testing protocols and labelling requirements for sunscreens sold in Australia. Importantly, this standard is based on in vitro (laboratory-based) testing methods rather than in vivo (human) testing.

The TGA mandates the following in vitro methodologies for compliance:

1. SPF Determination (in vitro): The SPF value of a sunscreen must be determined using a spectrophotometric method that simulates UV exposure through laboratory instruments. This method measures the product's ability to absorb or block UVB radiation using a standardised UV source and artificial substrate (such as PMMA plates).

2. Broad-Spectrum Assessment (in vitro): To make a "broad-spectrum" claim (indicating protection against both UVA and UVB radiation), the sunscreen must undergo in vitro testing to determine its critical wavelength, a measure of UVA protection. The test must confirm a critical wavelength of at least 370 nm, as specified by the standard.

Why In Vitro Testing is Used in Australia: Australia has taken a strong ethical and scientific stance by prioritising in vitro testing. The reasons include:

- Avoiding human exposure to potentially harmful levels of UV radiation
- Reducing variability associated with in vivo testing, which can differ across individuals, labs, and application techniques
- Streamlining compliance with a method that is more cost-effective and reproducible for both local brands and regulators

Is In Vivo Testing Used or Referred to in Australia? While in vivo testing (such as ISO 24444:2019) is considered the global gold standard for SPF determination, particularly in the European Union, the United States, and parts of Asia, it plays a limited and non-primary role in Australia.

To clarify:

1. In vivo SPF testing is not required by the TGA. The TGA does not mandate or prefer in vivo human testing for SPF labelling. All required SPF and broad-spectrum determinations must be made using in vitro methods as outlined in AS/NZS 2604:2021.

2. In vivo testing may be referred to or used in specific circumstances:

- For global brands marketing in multiple countries, in vivo SPF results (from ISO 24444) are often included in the product dossier. These may support marketing claims, especially where in vitro results show borderline compliance.
- Some contract testing labs may still offer in vivo testing to align with international regulatory standards, particularly when launching the same product in both Australia and overseas markets.
- The TGA may accept in vivo data as supporting evidence, but it will never replace or override the in vitro requirements under AS/NZS 2604:2021 for a product's SPF claim in Australia.

3. Ethical considerations limit in vivo use in Australia: Because in vivo testing involves deliberately inducing sunburn (erythema) in human volunteers to assess sunscreen effectiveness, its routine use is ethically discouraged unless absolutely necessary.

Australia (TGA)

In Australia, most sunscreens are regulated as therapeutic goods by the Therapeutic Goods Administration (TGA) if their primary purpose is UV protection. Such products must be entered in the Australian Register of Therapeutic Goods (ARTG) before sale. A sponsor (usually the brand or distributor) is legally required to hold evidence substantiating the SPF claim at the time of listing in the ARTG. This typically means the company must have conducted accredited SPF testing (according to the Australian standard) on the final formulation and packaging.

The Australian/New Zealand Standard (AS/NZS 2604:2021) governs sunscreen testing and labeling in Australia. It incorporates internationally recognised ISO-derived protocols but uses validated in vitro methods for both SPF determination and broad-spectrum assessment. Unlike other jurisdictions such as the EU and US, the TGA does not require in vivo testing for sunscreen products. Sponsors must hold in vitro test data that complies with this standard at the time of ARTG listing.

Key Australian labelling requirements include:

- **SPF Values and Categories:** Australia permits labels of SPF50+ as the highest category, indicating “Very High” protection. Per the standard, a product must test at SPF60 or above to claim “50+”, while SPF30 to 50 is considered “High protection”, products testing **SPF10 to 29** only offer “Moderate protection”. Labels must accurately reflect the tested category, it’s unlawful to overstate the SPF.
- **Broad-Spectrum and UVA:** In Australia, under AS/NZS 2604:2021, a sunscreen can be labelled "broad-spectrum" only if it demonstrates adequate UVA protection, using the critical wavelength method. Specifically, a product must achieve a critical wavelength of ≥ 370 nm, which indicates substantial UVA absorption across the UVA spectrum.
- **Water Resistance:** In Australia, sunscreens can carry specific water resistance claims, such as “Water Resistant 2 hours” or “4 hours” only if validated using the in vitro testing methods prescribed in AS/NZS 2604:2021 - Section 7.3: Water Resistance Testing.

The test simulates real-world water exposure by immersing the sunscreen-coated substrate (typically PMMA plates) in water for defined durations, for example, four 20-minute immersion cycles for a 4-hour claim. After immersion, the sunscreen’s SPF is re-evaluated using spectrophotometric analysis, and it must still meet or exceed the labelled SPF value.

This method ensures that a product retains its protective function after water exposure without requiring human testing. Australia’s allowance for 4-hour water resistance is longer than the US FDA’s 80-minute maximum and reflects the demands of Australia’s climate and outdoor lifestyle.

- **Label Information:** Because many Australian sunscreens are considered medicines, the labels must also include an AUST L or AUST R number (identifying their ARTG listing), detailed usage instructions, and warnings. TGA’s labelling code (TGO 92) and advertising code apply. For example, it’s mandated to include directions such as “apply 20 minutes before sun exposure” and warnings like “reapply every 2 hours”. Any therapeutic claims (like “prevents premature skin aging”) must be permitted by TGA.

- **Prohibited/Restricted Claims:** Under the TGA’s Advertising Code and AS/NZS 2604:2021, sunscreen labelling must be truthful and not misleading. Terms such as “sunblock”, “100% protection”, “waterproof”, and “sweatproof” are not permitted, as they imply absolute or indefinite protection, which no sunscreen can provide. Only substantiated claims, such as “Water Resistant (2 hours)” or “Water Resistant (4 hours)” are allowed, and must be supported by validated in vitro testing. The TGA enforces these restrictions to protect consumers from overestimating the level of protection provided by sunscreen products.
- **Approval Process:** Unlike the US, Australia does not pre-approve each sunscreen’s efficacy before marketing, but the ARTG listing process is a form of pre-market control. Sponsors attest that their product meets all requirements (including passing the required tests). The TGA can audit this evidence or request it during compliance reviews. However, this system relies heavily on the accuracy and honesty of the sponsor’s submitted data. Without routine independent verification, there is potential for variability in test outcomes and undetected non-compliance, particularly if sponsors use different laboratories, test early formulations rather than final batches, or delay re-testing after changes. This gap places the onus on brands and manufacturers and may contribute to inconsistent SPF performance in the marketplace.

In summary, Australia’s sunscreen regulations are distinct in that they mandate the use of validated in vitro methods, not in vivo testing, for both SPF and broad-spectrum assessment, as outlined in AS/NZS 2604:2021.

All primary sunscreens (products whose main purpose is UV protection) are regulated as therapeutic goods and must be listed on the Australian Register of Therapeutic Goods (ARTG). These products must demonstrate a minimum SPF of 4, but to claim “high protection” or “very high protection,” they must meet higher thresholds such as SPF30 or SPF50+ using in vitro spectrophotometric testing.

Secondary sunscreens, such as moisturisers or foundations with SPF, may be regulated as cosmetics if they meet specific criteria, but they must still comply with labelling and testing requirements when making SPF claims.

While the TGA does not pre-approve each product’s efficacy, it requires that sponsors hold robust evidence at the time of listing, and can request this data at any time. The system relies on sponsor integrity and proper evidence management, with regulatory action enforceable in cases of misleading or unsubstantiated claims

Compliance and Auditing in Australia: Current System and Effectiveness

Australia’s Therapeutic Goods Administration (TGA) is regarded as having some of the strictest requirements for sunscreen testing. However, the compliance and post-market auditing system has limitations that are now under scrutiny. Under current regulations:

- **Evidence at Listing:** When a sponsor lists a sunscreen on the ARTG, they must certify they hold evidence for the product’s SPF, water resistance (if claimed), broad-spectrum compliance, and stability. The TGA can request this evidence at any time. In practice, a dossier including the accredited lab reports for SPF and UVA tests, as well as stability test data (usually 3 months accelerated and/or real-time data), should be on file.

- **Good Manufacturing Practice (GMP):** Manufacturers of therapeutic sunscreens must adhere to pharmaceutical GMP standards. The TGA conducts inspections of manufacturing sites for quality control processes. Audits focus on whether companies consistently produce according to the tested formula and maintain quality systems. One outcome of GMP audits is to ensure that the concentration of actives in production batches matches the formulation that was tested for SPF. (For instance, a GMP audit might check batch records to confirm the correct percentage of zinc oxide or octocrylene was added.) Sites that fail GMP compliance can lose their license to manufacture or have their products deregistered. These manufacturing audits are an important, if indirect, mechanism to keep products in spec.
- **Lack of Routine Product Testing by TGA:** The TGA does not routinely conduct its own SPF testing on sunscreens, either before or after they reach the market. While some countries rely on in vivo (human) methods, Australia uses in vitro testing exclusively under AS/NZS 2604:2021, which eliminates the need for human subjects. Despite this, the TGA does not routinely perform in vitro testing either, even though the method is ethically sound and technically feasible. Instead, the TGA relies on sponsors (the product’s manufacturer or distributor) to generate and hold the required test data at the time of listing on the ARTG.

The regulator may request this data at any time but does not independently verify it unless concerns are raised. The TGA has stated it “does not conduct human or animal testing,” and has only outsourced SPF testing to accredited laboratories in limited circumstances, usually in response to a complaint, a media investigation (such as the CHOICE report), or suspected non-compliance.

In practice, this means there is no systematic or random audit testing of sunscreens on the market, despite the availability of in vitro testing methods that could be used to strengthen post-market surveillance.

- **Reactive Investigations:** When a third-party test (such as the recent CHOICE consumer test) suggests a product isn’t meeting its SPF, the TGA can trigger a compliance investigation. This may involve ordering the sponsor to conduct a fresh independent test, or the TGA commissioning a test at an external lab and demanding samples. The TGA can also check if the sponsor’s original evidence was adequate, for example, was the testing done on the exact formula? Was it done recently and on production batches, not just lab prototypes? If a product is found to genuinely underperform, the TGA has powers to mandate a recall or force corrective actions (such as relabelling or reformulation), and the company could face penalties for false or misleading claims under therapeutic goods law.
- **Role of the ACCC:** Parallel to the TGA’s own actions, the Australian Competition and Consumer Commission (ACCC) may get involved if there’s potential misleading conduct. The ACCC’s mandate is to ensure businesses do not make false claims to consumers. In the context of sunscreens, if a product advertised as “SPF50+” consistently only delivers SPF30 in reality, that could breach consumer law. Indeed, after CHOICE published its findings, they referred them to the ACCC to assess whether misleading claims were being made. The ACCC can pursue companies for fines or enforceable undertakings separate from the TGA’s regulatory actions. The existence of this parallel path means sunscreen companies in Australia answer to both a health regulator (TGA) and a consumer protection regulator (ACCC) regarding their claims.

Assessment of Effectiveness: The current system has ensured that all sunscreens on the market are at least tested once according to strict protocols, and that obvious non-compliance (like using banned ingredients or grossly mislabelling SPF) is rare. However, there are clear and known gaps in ongoing oversight.

The reliance on sponsor-provided data means that if a company's internal testing was flawed or if formulation changes occurred over time, regulators might not catch it unless someone complains or retests the product years later.

The TGA's reactive stance ("investigate when necessary") may not be sufficient for a product as critical as sunscreen, where performance can drift due to the factors discussed earlier (ingredient degradation, batch variation).

The CHOICE investigation in 2025 found 16 out of 20 sunscreens didn't meet their label claims in its tests. While some of those results might be due to lab-to-lab variability, the sheer number raised alarms. It indicates that some products in the market may be providing lower protection than promised for potentially years before detection.

The fact that one product (Ultra Violette's) tested as low as SPF5 in the CHOICE test, an extreme case, suggests a serious lapse either in manufacturing or in the original test accuracy. Companies disputed the findings, citing their own tests that show compliance, which highlights the variability issue again. But even taking variability into account, experts like John Staton (a respected Australian sunscreen testing expert) commented that while some variation is normal, we "should not see large variations" of the magnitude observed, and any product testing below its claim "should be addressed by the company and regulator".

Currently, the auditing system relies on trust and post-market checks rather than continuous verification. There is no routine annual re-testing of products by an independent body. Once on the ARTG, a sunscreen might never be tested again unless someone raises a red flag. Given that formulas can drift and new batches might not be identical to the tested batch, this is a weakness. The effectiveness of the system is further called into question by the need for external bodies like CHOICE to uncover these discrepancies.

In conclusion, Australia's compliance system has strong standards on paper, but its auditing/enforcement strategy is mostly reactive. It has been somewhat effective in ensuring initial quality (Australia doesn't, for example, have the kind of "sunscreen scandals" where unknown filters are used, the issues are subtler, about degree of protection). However, there is a clear need for more proactive measures to maintain trust.

The TGA's prompt statement that it will investigate and take action is reassuring, but prevention is better than cure. This analysis underlines that improvements, like periodic checks or stronger industry self-regulation, are needed to bolster the effectiveness of Australia's system.

Common Industry Challenges Impacting SPF Compliance

From a manufacturer's perspective, several challenges make it difficult to consistently meet labelled SPF claims and to prove compliance:

- **High Testing Costs:** In vitro SPF testing, while less complex than in vivo methods used overseas, can still be costly and time-consuming. Each validated test — conducted using specialised substrates and spectrophotometric equipment in accredited laboratories — can cost several thousand dollars per product. These costs increase further when multiple tests

are required, such as to validate different batches, confirm post-stability performance, or re-test after minor formulation adjustments. For small or independent brands, the financial burden of repeat testing can be prohibitive, leading many to rely on a single test conducted during product development. Although the TGA requires that evidence is held at the time of ARTG listing, there is no mandate for batch-by-batch verification, and many brands choose not to re-test unless there is a regulatory requirement or issue. The limited number of accredited labs offering AS/NZS 2604:2021-compliant testing can also lead to scheduling delays, particularly during peak production periods. In short, while in vitro testing avoids the ethical and logistical challenges of human trials, the cost and access barriers still limit widespread adoption of robust, ongoing verification practices across the industry.

- **Variability in Test Outcomes:** As discussed, SPF testing inherently has variability. This poses a challenge to industry, a company could diligently test its product and get an SPF50 result, yet a different lab or a re-test might yield SPF45. Companies must decide what SPF number to put on the label given this uncertainty.

Many will label conservatively to stay on the safe side, but competitive pressure (see next point) can push towards the highest claim. The variability also means that a “fail” in one test might not mean the product is truly sub-standard, but rather within normal statistical variance. It’s expensive and time-consuming to resolve such disputes (for instance, commissioning multiple tests in different labs). This can lead to inconsistent outcomes, where one product shows different results across labs, undermining both consumer trust and brand confidence in the testing process. Until testing methods become more reproducible, this will remain an ongoing challenge; brands sometimes legitimately feel they have an SPF50 product but cannot consistently demonstrate it every single time.

- **Reliance on Sponsor-Provided Data:** In Australia, sunscreen compliance relies heavily on sponsor-held data. The TGA does not routinely test products for SPF accuracy; instead, it requires sponsors to hold validated evidence, including in vitro test results conducted according to AS/NZS 2604:2021, at the time of ARTG listing.

This reliance can become problematic if a company conducts testing on a prototype formula that differs in composition from the final commercial batch, or if formulation changes occur later (e.g. a new UV filter supplier or excipient swap) without re-validation. While testing may be outsourced to international laboratories, the data must comply fully with AS/NZS 2604; test results based on alternative international protocols, such as ISO 24444, are not acceptable for regulatory purposes in Australia.

Overconfidence in outdated or non-aligned test data can result in SPF claims that no longer reflect actual product performance. Without routine independent verification by the regulator, this system places a high burden on sponsor integrity — and in rare cases, creates a risk that non-compliant products reach market without detection.

- **Batch-to-Batch Variability:** Formulating and manufacturing sunscreens is a delicate process. Small variations in ingredient lots, particle size of mineral filters, dispersion quality, or filling equipment can potentially affect SPF. While GMP ensures consistency within certain tolerances, the reality is that not every batch is identical. A formulation that passed SPF testing with flying colors could underperform if, say, the homogenisation step during manufacturing was slightly insufficient and the zinc oxide isn’t as evenly distributed.

Most companies do not SPF-test every production batch. They rely on process controls. But this means if something goes wrong in one batch, it might not be caught before distribution. Only later (through complaints or testing) would it be known. This is a challenge especially in high-volume manufacturing or when scaling up a formula from lab to factory, maintaining that same level of dispersion or emulsification can be tricky.

- **Ingredient Supply and Reformulations:** Over time, a brand might change suppliers or tweak formulas (for instance, if an ingredient becomes unavailable or new technology arises). Each change ideally should be re-tested for SPF, but doing so for every minor change is burdensome. Some brands skip re-testing if the change is deemed minor (e.g. a new fragrance or a swap of preservative), yet even “inert” changes can sometimes affect SPF by altering the emulsion stability or penetration of actives. The cost and time of testing can thus delay innovation or, conversely, lead to untested iterative changes if a brand is not extremely disciplined.
- **Competitive Pressures and Marketing Claims:** The market trend has been towards higher SPF numbers, as consumers often equate higher SPF with better protection. This creates pressure on companies to attain and advertise the highest SPF possible with their formulation. Achieving SPF50+ versus SPF30 might involve additional filter content (which can compromise aesthetics or increase cost) or using new filter combinations.

A challenge here is that some brands might push right up to the borderline, formulating a product that just hits SPF50 in testing to have the coveted “50+” on the label. If anything about the test conditions or later batches is slightly off, that product could fall into the 40s.

Economic and marketing incentives may unintentionally encourage risk-taking: a higher claim sells better, but comes with less margin for error. This was evidenced by at least one case in the CHOICE report where the most expensive, high-SPF product massively underperformed, suggesting the possibility that the formulation was optimised for user feel more than a safety buffer in SPF.

Smaller companies also might not have the R&D resources to fine-tune a stable SPF50+ formula on the first try; they might trust a contract manufacturer’s word that it’s SPF50+ without fully vetting it due to the cost of multiple tests.

- **Access to Accredited Testing:** In Australia, all SPF and broad-spectrum testing must be conducted using in vitro methods in accordance with AS/NZS 2604:2021. However, the number of accredited laboratories offering this specific testing is limited, which can create bottlenecks in scheduling, especially in the lead-up to summer or during peak production periods. This limited capacity may delay product development timelines or re-testing after formulation updates or stability checkpoints.

While overseas laboratories may be used, they must strictly follow AS/NZS 2604:2021 protocols for the results to be valid for TGA compliance, and many international labs still operate under ISO or FDA methods, which are not accepted in Australia. Brands must also consider challenges such as long sample shipping times, temperature control during transit, and the inability to directly supervise the testing process, all of which may impact data integrity. Expanding local testing capacity and ensuring uniform training and calibration across labs would significantly support more timely, consistent, and accessible SPF verification for Australian manufacturers.

In summary, while the industry strives to put out effective sunscreens, these challenges make it a non-trivial task to guarantee every bottle is up to spec. It's a perfect storm of scientific, economic, and regulatory factors. Understanding these challenges is important for crafting realistic solutions, for instance, any proposed reform should consider the financial and technical constraints companies face, and aim to support them in overcoming these hurdles rather than simply adding punitive burdens.

Recommendations for TGA and Industry Reform

To ensure sunscreens consistently meet their labelled SPF and to rebuild consumer confidence, a multifaceted approach is needed. Here we propose detailed, practical recommendations for both regulators (like the TGA) and the industry. These recommendations draw on the issues identified and aim to enhance oversight, transparency, and quality without unduly stifling innovation or access.

- **1. Implement Periodic Independent Batch Testing:** Rather than relying solely on pre-market testing, regulators should institute a program of ongoing surveillance testing. For example, the TGA (or a designated independent body) could randomly select sunscreen products from the market each year and subject them to full SPF testing at an accredited lab. This “spot check” approach would act as a deterrent against underperforming products and catch problems early.

The frequency and scale could be risk-based, e.g. test more products during summer or focus on high-SPF claims. If a product is found to be significantly below its claim, the regulator can mandate a broader investigation (testing multiple batches) and corrective actions (like recall or relabelling). CHOICE's recent test put a spotlight on this need, effectively doing what a regulator might do; institutionalising it would formalise the process. While the TGA notes it has outsourced testing “where necessary”, making it routine (even if for a sample of products) would strengthen compliance.

One idea is a “proficiency testing” model: require companies to submit a sample from a real production batch to an independent lab annually. This could even be done via a third-party certification program. The outcome of such periodic tests could be shared publicly, adding pressure on brands to maintain quality. Regulators would need funding to support this, but it directly protects public health. Internationally, other countries could adopt similar measures; in the US, the FDA has considered requiring firms to keep records of batch testing, which could be coupled with audits.

- **2. Enforce Long-Term Shelf-Life Monitoring:** It's not enough for a sunscreen to pass tests at launch, it should remain effective until its expiration date. Regulators should require stability protocols that include SPF testing after accelerated aging (e.g. after 3 months at 40°C/75% humidity, or after UV exposure to simulate a year of occasional sun) to ensure actives haven't degraded.

Many companies already do basic stability for physical changes, but verifying SPF at end-of-life would be a game changer. Additionally, real-time shelf-life studies could be mandated for critical products: e.g., a company retains samples from each batch and tests the SPF at the mid-point and end-point of the product's lifespan. If any significant drop is observed, it would trigger an investigation or early expiry.

To support this, guidelines on how to do photostability testing (like exposing samples to a certain dose of UV in a solar simulator and then testing SPF in vitro) can be developed.

Ultimately, shelf-life monitoring ensures that the number on the bottle is valid not just on day one, but on day 1000 as well. It addresses issues like ingredient degradation, packaging interactions, and preservative failure. Companies might need to invest in stability chambers and periodic testing, but this investment pays off by preventing efficacy drop-offs. Regulators could check compliance by auditing stability data during inspections.

- **3. Subsidise Access to Testing Facilities:** Government and industry bodies should work together to reduce the financial burden of rigorous testing, especially for smaller brands. One recommendation is to establish a national sunscreen testing facility (perhaps under a government research organisation or a university) that offers SPF and UVA testing at cost-price or via subsidies. The TGA or Health Department could provide grants or vouchers to small Australian manufacturers to cover part of their testing expenses. Another approach is collective bargaining: industry associations (like ABIC or Accord Australasia) could negotiate group rates with labs or organise round-robin testing programs where multiple products are tested in one panel to share costs.

Subsidised testing lowers the barrier for companies to do the *right thing*, such as re-testing after reformulation or running a confirmatory test on a production batch. It would especially help for periodic batch testing and stability tests recommended above. In the long run, investing public funds here is justified by the public health benefit (preventing skin cancer through effective sunscreens). Also, supporting local testing capabilities means companies aren't forced to send samples overseas, keeping quality control within closer reach.

- **4. Enhance Label Transparency and Consumer Information:** Empower consumers and professionals with information that fosters trust. We suggest a few labelling and disclosure improvements:
 - **Disclose Testing Date or Batch:** Include on packaging or the company's website the date (or batch number) of the formulation that was tested for SPF. For example, "SPF50+ (tested on formula batch from June 2025)". This alerts consumers that the brand is monitoring SPF. If a product has been on the market unchanged for years, savvy consumers or regulators might prompt the brand to re-test if the last test was, say, 5+ years ago.
 - **Actual SPF Values in Documentation:** Allow (or encourage) companies to state in product literature the actual average SPF result if it exceeded the claim. E.g., a product might be labelled SPF50+ but the test result was SPF72, the company could mention this in a brochure or website. Some brands already voluntarily do this to show a margin of safety. It must be communicated carefully to not confuse shoppers, but it can increase confidence that SPF50+ truly means "well above 50" in such cases.
 - **Broader Protection Indices:** Consider adopting or publicising additional metrics like UVA star ratings (used in the UK) or the UVAPF value. The Australian standard currently only requires meeting broad-spectrum pass criteria, but a stronger transparency move would be to let consumers know if a product has, for instance, UVAPF 20 vs UVAPF 10, even if both pass the basic requirement. Similarly, water resistance performance could be more explicitly labelled (like "very water resistant – 4 x 20 min immersions" to educate users that it was rigorously tested).

- **Expiration and Storage Advice:** Make the expiration date clearly visible (many already do this). Include a note on storage (e.g. “Store below 30°C” on all sunscreen labels), this is often in the fine print but should be more prominent if heat can ruin the product. If a product is in potentially light-permeable packaging, perhaps a note like “Keep container out of direct sun when not in use” could be added, aligning with the idea that packaging plus user care preserves quality.
- **ABIC or Quality Seal:** Industry associations might create a voluntary “Quality Checked SPF” seal that brands earn by submitting products for extra testing or adhering to higher standards. This could appear on packaging or marketing materials to signal that a product underwent additional independent verification beyond regulatory minimums. It’s similar to how some products carry endorsements (like Cancer Council recommendations, etc.), and could be a way to rebuild trust by showing an extra layer of accountability.

Overall, better transparency on labels and in marketing will allow consumers and industry professionals to make informed choices and pressure companies (by voting with their wallet) to maintain high standards. It moves the system from “trust us” to “see for yourself, here’s the proof”.

- **5. Strengthen Compliance Auditing and Penalties:** Regulators should wield a bigger stick for deterrence, while also providing clear guidelines to industry on what is expected. The TGA could increase random audits of companies’ SPF test data, not necessarily testing the product in lab, but auditing the paperwork more frequently. For example, periodically ask companies to submit current certificates of analysis or any out-of-spec results they’ve obtained. If a company knows that any given year the TGA might ask “show us your latest SPF test report”, they are more likely to ensure they have a recent one. Additionally, if a company is found to not have evidence, the penalties should be significant (e.g., cancellation of ARTG listing, fines). Currently, such penalties exist in law, but enforcement could be more visible to set examples.

The ACCC’s involvement is also crucial: clear consequences for misleading claims (possibly consumer-level refunds, public recalls, or corrective ads if a product’s claim is proven false) will motivate compliance. Essentially, make the cost of non-compliance (reputationally and financially) higher than the cost of doing proper testing. The TGA’s investigation after CHOICE’s findings is a good step; we recommend formalising that process so that any significant discrepancy found by credible third parties is automatically reviewed, and if substantiated, leads to swift action like label corrections or product suspensions until fixed.

- **6. Encourage Innovation in Testing and Collaboration:** The long-term solution to variability is better science. We recommend that the TGA and industry partners actively participate in international efforts to validate in vitro SPF test methods. Australia could even lead by funding research (through CSIRO or academic grants) into correlative in vitro methods or wearable skin sensors that measure UV dose in real time on humans.

Until then, interim measures like cross-lab validation should be encouraged: e.g., a guidance that if a product is high SPF, testing it in two different labs could give a more robust claim. Industry can collaborate by sharing anonymised data on how various labs correlate, thus identifying any labs that might be outliers and improving overall consistency.

Another innovative angle is post-market monitoring with technology: some research is exploring if one can deduce sunscreen performance from real-world usage data or wearable

UV dosimeters on consumers, while that's experimental, staying open to new compliance tech is important.

- **7. Industry Training and Standards:** The industry should raise the bar internally. We recommend an industry-led training program for formulators and quality assurance teams focused on sunscreen efficacy. This could cover best practices for maintaining SPF in formulation (e.g., how to properly disperse zinc oxide, which filters stabilise each other, etc.), and how to design robust testing regimes. If every company formulates with these best practices, failures will be fewer. Additionally, creating a standard operating procedure (SOP) for when a company should re-test (for instance, any change in active ingredient source, or every X batches or X months) would be useful. ABIC and other bodies can develop such SOPs as guidelines.

Each of these recommendations comes with considerations of cost and feasibility, addressed in the next section. Importantly, they should be seen as complementary parts of a cohesive approach, regulatory oversight (points 1, 5) works hand-in-hand with industry proactivity (points 3, 7) and transparency (point 4) to create a system where sunscreen label accuracy is ensured from multiple angles.

Cost and Feasibility Considerations

Every reform must balance benefit with practicality. Here we discuss the implications of the above recommendations:

- **Periodic Testing Costs:** Conducting full SPF tests is expensive. Funding periodic independent tests (recommendation 1) will require resources. A possible model is a co-funded scheme: government covers some costs as a public health investment, and perhaps a small levy on sunscreen sales contributes as well. The logistics (recruiting volunteers, lab throughput) mean it's not feasible to test dozens of products each month; a focused approach (maybe 10-20 products per year targeted) could be a start. The cost per test might be in the order of \$5,000–10,000, so testing 20 products is a ~\$100-200k annual program – not insignificant, but minor relative to the healthcare costs of skin cancer.

If even one test identifies a sub-SPF product that tens of thousands of people use, it could prevent health risks and liability. So the cost is justified, but funding would need allocation. Feasibility is high if done on a small, strategic scale annually.

- **Industry Testing Burden:** For companies, implementing shelf-life testing and more frequent batch verification (recommendation 2) means increased in-house QA costs. Stability chambers, additional lab work (possibly using in vitro screening methods where possible to reduce cost) will be needed. For large manufacturers, this is doable within existing QC budgets (they often do extensive stability for global markets already). For smaller brands, this might be challenging, which is why recommendation 3 (subsidies and shared facilities) is crucial. Providing a low-cost testing option can ease this burden.
- **Batch Testing and Feasibility Considerations:** In Australia, in vitro testing is the regulatory standard for SPF and broad-spectrum verification under AS/NZS 2604:2021, and full in vitro testing of every production batch is not required by the TGA. However, due to the cost and time involved in formal laboratory testing, many manufacturers do not routinely test every batch. To support interim quality control, companies may use in-house screening methods,

such as UV absorbance checks or visual inspection of dispersion to identify potential formulation inconsistencies before sending a sample for formal testing.

The feasibility of stronger batch-level oversight could be improved if faster, low-cost in vitro indicative tests were validated and standardised for this purpose. Such tools could give formulators early warning that a batch may fall outside expected performance, prompting corrective action or confirmatory lab testing before release. Supporting method development in this area would improve both compliance and confidence in real-world product consistency.

- **Subsidy and Facility Feasibility:** Setting up a national testing facility (part of recommendation 3) would have upfront costs (equipment, hiring experts). It could be integrated into an existing lab or agency to save infrastructure costs. Running costs could be offset by charging a modest fee per test, with government covering capital costs. A public lab might also drive down the market price of testing through competition. The subsidy approach, is straightforward to implement via an industry grant program. It would need oversight to ensure the money is used for testing in accredited labs. The main challenge is securing government commitment for funding, which likely requires advocacy by industry and public health groups highlighting how such support will yield safer outcomes and innovation (smaller businesses can formulate confidently knowing they can afford testing). Considering that skin cancer treatment in Australia costs the healthcare system on the order of hundreds of millions per year, investing a fraction of that in prevention (through better sunscreens) is economically sound.
- **Label Changes and Transparency:** Enhancing labels (recommendation 4) has minimal direct financial cost, it's more about regulatory adjustments and consensus. There might be concern from some companies that publishing actual SPF results or test dates could expose them to criticism (e.g., if a test came back just barely at the threshold). However, those are precisely the cases where transparency is needed. Feasibility is high since it mostly involves updating standards and educating marketers. One risk is information overload on labels; this can be mitigated by using online disclosures or QR codes for detailed info, keeping the packaging itself user-friendly. Regulators would need to update labelling guidelines (TGA could, for example, amend Therapeutic Goods Order 92 or the sunscreen standard to encourage these disclosures). This is more of a policy decision than a resource issue. Consumer research might be needed to ensure the additional info is understood correctly (for instance, "50+ (tested 2023)" – consumers should read that as positive, not as an expiration of validity).
- **Enforcement and Auditing Resources:** Strengthening compliance audits (recommendation 5) means the TGA and/or ACCC will spend more effort and time on sunscreens. TGA would need to allocate officers to follow up regularly, perhaps by creating a dedicated "sunscreen compliance team" especially during the lead-up to summer. This is feasible with modest increases in staffing or by prioritising high-risk products (like new brands or very high SPFs) for audits. Penalties and actions (like recalls) can actually save costs in the long run by preventing ongoing sale of substandard goods. The legal frameworks are already in place; it's about executing them more often. One feasible approach is to integrate sunscreen checks into routine pharmacy or retail audits (if the TGA does those for medicines). The ACCC involvement typically kicks in when there's a major breach; ideally, proactive TGA action would mean ACCC only rarely needs to intervene. The public nature of enforcement could have a big deterrent effect at basically zero cost.

- **Industry Uptake:** Many of these reforms rely on industry buy-in. Feasibility is highest if companies see the value, not just in avoiding punishment but in market advantage. If early adopter brands start advertising that they have “independent verification” others might follow to stay competitive. The cost for a company to implement additional testing and transparency might initially seem like a burden, but those who do could gain consumer trust and loyalty, which is financially beneficial. It’s important that reforms aren’t seen as only punitive; they also present an opportunity for brands to differentiate themselves by quality.

In summary, the recommendations are achievable with a combination of regulatory will, industry collaboration, and targeted funding. The costs involved (testing, monitoring) are relatively small in the context of the sunscreen market size and the health stakes.

Phased implementation can help manage feasibility: for instance, start with voluntary programs or pilot studies (maybe the TGA could pilot a random testing program on a small scale and demonstrate its effectiveness, then seek expansion). Over time, as improved methods become available, the costs of compliance should actually decrease, making it easier to maintain these high standards. The most important feasibility factor is coordination: regulators, industry bodies, testing laboratories, and consumer groups will need to communicate and cooperate to put these ideas into practice effectively.

Conclusion and Framework for Ensuring Trust in Sunscreen SPF

Key Findings: Sunscreens are complex pharmaceutical/cosmetic products where formulation science, testing methodology, and regulatory policy intersect. This report has found that numerous factors, from unstable ingredients and packaging that doesn’t fully protect the formula, to the intrinsic variability of human testing, can cause a sunscreen to underperform relative to its SPF label.

The gaps in Australia’s current system mean that some products on the market may not deliver the promised level of protection, potentially eroding consumer trust and putting users at risk. On the other hand, it’s clear that Australia has rigorous standards on paper, the main issues are in consistent enforcement and the practical challenges companies face in meeting those standards continuously.

We also identified that the industry faces challenges like high testing costs and pressure to maximise SPF claims, which can inadvertently incentivise borderline practices. However, these are challenges that can be addressed with targeted reforms and a culture shift towards greater transparency and quality assurance.

Proposed Framework for Skincare Brands: To ensure consumer trust and compliance, skincare brands (manufacturers and marketers of sunscreens) should adopt a proactive quality framework that goes above the minimum regulatory requirements. From the perspective of a formulator and industry leader, here is a framework that brands can implement:

- **Design for Efficacy and Stability:** It starts at R&D, formulate with an eye not just to achieve a high initial SPF, but to maintain it. This means choosing photostable combinations of filters (e.g. stabilise avobenzone with octocrylene and antioxidants, use mineral filters with proper coatings), adding ingredients that boost film formation and water resistance (polymer film formers, etc.), and avoiding ingredients that might interfere with UV filters (certain fragrances or plant extracts can sometimes destabilise formulas).

Set an internal goal to formulate to a higher SPF than needed so that even with some degradation or variability, the product remains at least at the label claim.

Testing during development should include not just fresh SPF, but stress tests: expose lab samples to heat and UV, then test SPF to see if it drops. That way, formulators can catch instability early. In short, build a margin of safety into the product.

- **Robust Verification (Test, Test, Test):** Brands should incorporate verification at multiple stages:
 - **Pre-market Validation:** Test the final formulation with at least one (preferably two) independent labs to confirm SPF results. If results vary, investigate why and reformulate or retest as needed. Do not simply cherry-pick the highest result; ensure the claim is supported by a consensus of data. Also verify UVA compliance (get the UVA-PF value) and test water resistance if claiming it. Keep all documentation ready for scrutiny.
 - **Ongoing Batch Testing:** For each major production batch or at a set frequency (e.g. one batch per quarter), perform a quick check. This could be as simple as an in vitro UV absorbance test compared against the original batch's profile. Some large companies already do in-house spectral scans of each batch as a quality check. If any batch's absorbance looks off, consider submitting it for an in vivo test or at least withholding it. If resources allow, do periodic full SPF tests on randomly selected batches (maybe one batch a year if you produce many). This aligns with our recommendation that ideally each product sees a lab periodically, whether mandated or voluntarily.
 - **Stability Monitoring:** Maintain retain samples from each batch in controlled storage. At 6 months, 12 months, etc., test critical parameters. If your product is close to expiry, do an SPF test to ensure it still meets SPF. If not, you might need to shorten the shelf life in future or improve the formula. This kind of internal due diligence ensures you're never caught off guard by a third-party test.
 - **Documentation and Auditing:** Set up internal audits where, for example, a Quality Assurance manager must sign off that for each product the supporting SPF evidence is up-to-date and that no changes have been made without evaluation. Essentially, treat SPF like a "potency" that you'd monitor just as carefully as a pharmaceutical company monitors drug strength over time.
- **Packaging and Storage Controls:** As a brand, choose packaging that best preserves the product (even if it's a bit more expensive initially). Opt for opaque or UV-blocking containers, airless pumps, or tubes with good seals. If you switch to recycled materials, run extra tests to ensure they don't compromise the formula's stability.

On the distribution side, control your supply chain: ensure warehousing conditions aren't degrading your product (no prolonged heat exposure during shipping or storage). Many brands will, for instance, avoid shipping in peak heat waves or use refrigerated transport for temperature-sensitive stock. These measures keep the product within spec when it reaches the consumer. Also, communicate clearly to retailers and end-users about proper storage (e.g. "don't leave it in a hot car"). When the consumer is better informed, the product is more likely to remain effective.

- **Education and Clear Communication:** A reputable brand contributes to consumer education. This can mean providing clear instructions and safety information on labels (beyond regulatory minimums). For example, explicitly state “apply at least X amount” or include a diagram of where to apply. Encourage reapplication. These help ensure the product is used in a way that actually delivers the SPF on the label.

From a trust perspective, be transparent: if a consumer inquires about your testing, be ready to share details. Some brands publish summaries of their test results; doing so can set you apart as honest and scientifically driven. In the age of social media, if questions arise (as happened in the Purito case internationally where consumers doubted a sunscreen’s SPF), being forthcoming with data and action builds credibility.

- **Engage in Industry Initiatives:** Join industry associations such as ABIC, or programs that aim to self-regulate and improve standards. By being part of these groups, brands can stay ahead of regulatory changes, contribute to shaping sensible guidelines, and perhaps partake in group testing that validates products across the board. It’s also a form of collective security, if all reputable players are on board, it’s harder for a rogue product to slip through and tarnish the industry’s reputation.
- **Continuous Improvement Mindset:** Finally, foster a culture within the company that views compliance not as a checkbox but as an ongoing commitment. Keep abreast of the latest research (maybe your R&D reads up on new photostability findings or new SPF test methods). If a better way to ensure efficacy emerges, adopt it. Solicit feedback from customers, if multiple users report sunburns or issues, investigate immediately and don’t dismiss it as user error until proven. Essentially, be proactive and consumer-safety-focused at all times.

By implementing this framework, brands not only comply with regulations but actually exceed them, which in turn will likely become a marketable quality. Consumer trust, once lost, is hard to regain, but by taking these concrete steps, brands can demonstrate that their SPF claims are rock-solid. This will be increasingly important in Australia, given the public attention on sunscreen performance. Brands that follow this path will help elevate the whole industry’s reputation, ensuring that “Slip, Slop, Slap, Seek, Slide” remains effective advice backed up by reliable products.

This comprehensive analysis underscores that maintaining SPF integrity is a shared responsibility. Regulators must update and enforce rules effectively, and industry must uphold the highest formulation and testing standards. The recommendations and framework provided aim to close the gap between label and reality. By doing so, we protect public health and uphold consumer confidence in sunscreens, a product that is truly a lifesaver in the Australian sun.

See Below for additional information and references.

Additional Information:

Regulatory Testing and Labelling Requirements (EU, US)

Sunscreen products are regulated differently across jurisdictions, which affects how SPF claims are tested, approved, and monitored. For further comparative information, below is a analysis of the frameworks in, Europe, and the United States.

Europe (EU Commission)

In the European Union, sunscreens are regulated as **cosmetic products** under the EU Cosmetics Regulation (EC No. 1223/2009). There is no pre-market registration for efficacy, but manufacturers must ensure their products are safe and efficacious, and they must compile a Product Information File (PIF) with test data to substantiate all claims (including SPF). The European Commission issued a Recommendation 2006/647/EC on sunscreen efficacy and labeling, which, while not law, is treated as the de facto standard by industry and enforcement bodies. Key requirements and practices in the EU include:

- **Testing Methods:** The EU recommends the ISO 24444 in vivo SPF test for determining the SPF value. This ensures consistency across products in the EU market. Additionally, UVA protection must be verified. The widely accepted criterion is that the UVA Protection Factor (UVA-PF) must be at least 1/3 of the labelled SPF. This is typically measured by the Persistent Pigment Darkening (PPD) method or its ISO equivalent (ISO 24443 in vitro UVA test, which uses spectral absorbance methods). The product must also have a critical wavelength ≥ 370 nm (meaning the sunscreen’s absorption spectrum covers well into the UVA range). Together, these ensure “broad-spectrum” efficacy in EU terms.
- **SPF Label Categories:** EU labeling caps at “SPF 50+” for the highest protection category. The categories defined by the EC are generally: Low protection (SPF 6-10), Medium (15-25), High (30-50), and Very High (50+). As noted, any measured SPF above 50 is labelled as 50+. Manufacturers are expected to formulate such that the actual tested SPF is significantly above 50 (usually ≥ 60 , similar to Australia’s requirement) to use the 50+ label. This prevents unrealistic numbers on labels and avoids a false sense of security from claims like “SPF100” (which are banned in the EU).
- **Mandatory Warnings/Advice:** European sunscreens must carry standardised warnings and usage instructions. These include phrases like: *“Do not stay too long in the sun, even while using a sunscreen product”*, *“Keep babies and young children out of direct sunlight”*, and *“Over-exposure to the sun is a serious health threat”*. They also advise on application: *“Apply generously before sun exposure and reapply frequently, especially after swimming or sweating”*, with a caution that not applying sufficient quantity will markedly lower protection. These statements aim to educate consumers that sunscreen isn’t total protection and must be used correctly.
- **UVA Symbol:** If a product meets the EU’s broad-spectrum criteria (UVA-PF $\geq 1/3$ of SPF and critical wavelength ≥ 370 nm), it is entitled to display the “UVA” circle logo on the packaging. This symbol is now common on EU sunscreens, assuring consumers of decent UVA protection.
- **Prohibited Claims:** Similar to other regions, EU guidelines prohibit words like “sunblock”, “100% protection”, or claims that you don’t need to reapply. Waterproof/“all day” claims are forbidden; instead terms like “water-resistant” can be used if appropriate tests are passed

(water-resistance in EU is generally defined by a smaller 40-minute immersion test, and “very water-resistant” by 80 minutes, though EU product labels often just say “water-resistant” without specifying time).

- **Enforcement:** In the EU, there’s no central pre-market testing by a regulator, but each company’s responsible person must ensure compliance. Market surveillance authorities in each member state can and do test products on the market to verify claims. If a sunscreen is found not meeting its SPF, it can be considered a misleading claim under the EU Common Criteria regulation for cosmetic claims, and enforcement actions (including product recalls or fines) can occur. However, routine independent testing by authorities is limited; much depends on manufacturers’ diligence and occasional spot-checks by consumer organisations or regulators.

In essence, the EU places the onus on manufacturers to follow the harmonised standards. The regulations emphasise consumer information (hence the warning labels and UVA logo) and avoidance of exaggerated claims. The alignment with ISO methods means EU, Australian, and many international sunscreens are often tested in similar ways, facilitating global consistency for brands.

United States (FDA)

In the United States, sunscreens are regulated as Over-The-Counter (OTC) drugs by the Food and Drug Administration (FDA). Rather than requiring pre-market approval for each product (unless it’s a new active ingredient or formulation requiring a New Drug Application), the FDA uses a monograph system. The sunscreen monograph (21 CFR §352, and updates in 21 CFR §201.327 for labelling) specifies which active ingredients are generally recognised as safe and effective (GRASE) and sets the testing and labelling requirements for all sunscreen products.

Key points of the US system:

- **Active Ingredients and Formulation:** Only certain UV filters are allowed in US sunscreens (at specific concentrations) under the monograph. This list has historically been more restrictive than Europe; for example, Tinosorb S and M, Bemotrizinol, and other modern filters have not been GRASE-approved in the US (though FDA is reviewing data on some). The allowed actives include familiar ones like avobenzene, octocrylene, homosalate, octisalate, octinoxate, oxybenzone, zinc oxide, and titanium dioxide. If a company wants to use a new filter, it faces a drug approval process rather than the simpler cosmetic route used elsewhere.
- **SPF and Broad-Spectrum Testing:** The FDA mandates in vivo SPF testing very similar to the ISO method. A broad-spectrum test is also required: the FDA uses a critical wavelength method (in vitro) where a product must have a critical wavelength ≥ 370 nm to be labelled “Broad Spectrum”. If a sunscreen is not broad-spectrum (i.e., provides mostly UVB protection only), it must carry a warning that it doesn’t protect against UVA/skin aging. In practice, virtually all US sunscreens with SPF ≥ 15 attempt to be broad-spectrum. Notably, the FDA does *not* require a UVA protection factor of 1/3 of the SPF as the EU does. This means some US products can legally have very high SPF but relatively lower UVA protection (a point of critique by experts who note that UVA protection is not equally emphasised in the US system). The Boots star rating (used in the UK) or UVA-PF disclosure are not used in the US; only the broad-spectrum pass/fail is indicated.

- **Labelling Requirements:** US sunscreen labels are quite detailed due to drug regulations. They must include:
 - The SPF value (e.g. SPF 30 or SPF 50). If broad-spectrum, it usually says “Broad Spectrum SPF [value]”.
 - If water-resistant, it must specify “Water Resistant (40 minutes)” or “Water Resistant (80 minutes)” as appropriate. If not water-resistant, the label must direct consumers to use a water-resistant sunscreen if swimming or sweating.
 - The Drug Facts panel: an FDA-format box that lists Active Ingredients (with their percentages), Uses (e.g. “helps prevent sunburn”), Warnings (standard sunscreen warnings about UV exposure, skin cancer/aging alert for non-broad-spectrum or SPF below 15, stop use if irritation, keep out of eyes, keep out of reach of children, etc.), Directions (e.g. “apply 15 minutes before sun exposure... reapply at least every 2 hours...” and guidance on water exposure reapplication), and Other information (like storage temperature). In effect, a US sunscreen must look like an OTC drug label on the back.
 - Marketing claims are tightly controlled: the FDA prohibits terms like “sunblock”, “sweatproof” or “waterproof”, and absolute phrases such as “all-day protection”. Companies also cannot claim an SPF higher than “**SPF 50+**” under current FDA rules. The FDA’s 2011 sunscreen final rule stated that SPF values should be capped at 50+ because higher numbers were deemed misleading without sufficient evidence of added clinical benefit. (There was talk of allowing up to 60 or 80 in later proposals, but as of now, labels above 50 typically say “50+” or sometimes just “50” in compliance.) In practice, some US products have marketed SPF 70 or 100 in past years, but FDA guidance discourages this and may enforce the cap. The general understanding is SPF 50+ means anything 60 or above.
 - Water-resistance claims must be qualified with time. If a product passes the FDA’s water immersion test for 40 minutes, it can claim “water resistant (40 minutes)”; if it passes 80 minutes, “water resistant (80 minutes)”. No product can claim more than 80 minutes. After that, reapplication is mandated. The label also must instruct reapplication after 80 minutes of swimming or sweating, immediately after towel drying, and at least every 2 hours generally.
- **Regulatory Oversight:** A key difference in the US is that every formulation must be tested and the results kept on file by the manufacturer (or available to FDA). The FDA does not pre-approve sunscreen efficacy, but it can inspect records. In 2019, FDA proposed a rule to require companies to maintain SPF test results and make them available upon request. If a product is found not to meet its label (e.g., through FDA testing or other data), it would be considered misbranded and subject to regulatory action. However, routine FDA testing of products on the market has been limited. Much like Australia, issues often come to light via independent evaluations (for example, Consumer Reports in the US annually tests sunscreens and occasionally finds some that underperform their label claims). The burden is on manufacturers to ensure compliance, and companies face liability (lawsuits or FDA warning letters) if they knowingly market a subpotent product.

In summary, the US approach is stringent about labeling and formulation compliance under the drug framework, but the actual enforcement relies on the honor system with the looming threat of FDA action. The protective measures (like standardised Drug Facts and warnings) help educate consumers, while the testing requirements ensure broad-spectrum protection is considered.

The differences between the US and EU and Australia, particularly regarding UVA standards and maximum SPF claims, reflect slightly different philosophies: the US focuses on preventing over-claiming and ensuring minimum broad UVA coverage (critical wavelength), whereas the EU/Aus emphasise a balanced UVA/UVB ratio. Both systems aim to ensure that what's on the label is truthful, but gaps in enforcement can lead to instances where products slip through that don't truly meet the claimed SPF.

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