



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Consultation outcome: Improvements to the regulation of sunscreens in Australia

Overview of submissions received, the TGA's response and proposed regulatory reforms

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Introduction

The Therapeutic Goods Administration (TGA) conducted a public [consultation](#) from 26 March to 23 May 2026 which proposed a number of options to improve to the regulation of sunscreens in Australia.

Almost 120 consultation responses were received from industry, testing laboratories, health professionals, consumer groups, academia and other stakeholders. This paper provides a summary of stakeholder responses to matters raised in the consultation, along with the resulting reforms proposed by the TGA.



Please note that not all respondents provided a written component as part of their submissions.

Consultation matter 1A: Current SPF *in vivo* testing has variability issues

There is significant variability in results obtained using the current *in vivo* (human) Sun Protection Factor (SPF) testing method in International Organization for Standardization (ISO) 24444, and this variability increases with the SPF value. *In vivo* SPF testing is the current mandatory testing required for sunscreens. However, there are new recently published ISO methods that offer an alternative to *in vivo* testing.

Options proposed to address Issue 1A

- Option 1: Status quo: maintain the existing testing requirements for sunscreens.
- Option 2: Enable sponsors to comply with either *in vitro* or *in vivo* testing where appropriate.
- Option 3: Mandate *in vitro* SPF testing only, where appropriate.

Overall summary of stakeholder responses to matter 1A

Option 1: Status quo

Respondents who supported option 1 generally favoured retaining the current approach until alternative methods are better established. They considered *in vivo* testing important for real-world performance, water-resistance claims, certain formulation types and confidence in established SPF claims.

A recurring view was that recent sunscreen concerns should be addressed through stronger laboratory oversight, sponsor compliance and enforcement, rather than replacing the current testing pathway. Respondents identified accreditation, clearer expectations for testing facilities, audits and post-market checks as practical improvements.

Some respondents were cautious about moving too quickly to *in vitro* methods. Concerns included whether results translate across product types, variability between methods, and unresolved issues for mineral, stick, anhydrous and water-resistant products. Several supported *in vitro* testing only as a complementary method or during a transition period.

Option 2: Enable sponsors to comply with either *in vitro* or *in vivo* testing where appropriate

More than half of the respondents favoured option 2, which was generally seen as the most workable middle path. Respondents viewed it as allowing validated *in vitro* or hybrid methods where appropriate, while retaining *in vivo* testing for products or claims where it remains necessary.

Many respondents favoured option 2 because it would reduce reliance on human erythema testing, support more ethical practices and allow more consistent checking of SPF claims. Consumers and health stakeholders linked this to greater confidence in sunscreen labels and stronger public health protection.

Industry and international respondents valued the flexibility of this option. They noted that no single method is likely to suit every formulation, dosage form, market or claim, particularly for water-resistant products, mineral filters, sticks and other complex products. A flexible framework was seen as less likely to disrupt supply, create testing bottlenecks or limit product choice.

Implementation comments emphasised the need for clear TGA guidance on method selection, acceptable variability, margins of error, confidence intervals, retesting triggers, laboratory accreditation, water-resistance claims and treatment of existing *in vivo* evidence. Staged implementation, targeted audits and ongoing post-market monitoring were also commonly suggested.

Option 3: Mandate *in vitro* SPF testing only, where appropriate

Support for option 3 was generally based on stronger standardisation and a clearer move away from human-subject testing. Respondents considered *in vitro* testing more objective, scalable and ethically preferable where suitable for the product and claim.

A common theme was that mandated *in vitro* testing could help restore confidence in sunscreen claims by making testing more consistent and less dependent on sponsor choice. Respondents also noted potential for more frequent batch, shelf-life or lifecycle testing to confirm products continue to meet their claimed SPF.

Even among supporters of option 3, several respondents noted that the approach would need clear limits. Water-resistance claims, method validation, laboratory capacity, transition timing and acceptable variability would need to be resolved before any broad mandate could operate effectively.

Hybrid/no option selected

Some respondents did not select a single option and instead raised broader concerns. These comments generally supported a calibrated approach rather than a simple choice between the 3 models.

Common themes included understanding the root causes of recent sunscreen testing concerns, strengthening SPF testing reliability, improving documentation and traceability, applying proportionate accreditation requirements and explaining how any regulatory change would address the identified problems.

Across the responses, the strongest area of common ground was the need for greater confidence in SPF claims. While respondents differed on the preferred pathway, they consistently identified testing reliability, water-resistance limitations, laboratory competence, clear guidance, transition management and consumer protection as key issues to resolve.

TGA response to matter 1A

The TGA considers that consultation feedback demonstrates a clear need to improve confidence in SPF claims while recognising differing views on the most appropriate testing framework. The feedback shows broad agreement that variability in current *in vivo* SPF testing should be addressed; however, respondents differed on whether this should occur through strengthened oversight of the current framework, a flexible hybrid approach, or a transition to *in vitro* testing. Nonetheless, a little over half of the respondents favoured the option to enable sponsors to comply with either *in vitro* or *in vivo* testing where appropriate.

The TGA considers that maintaining the current framework without further regulatory action would not adequately address stakeholder concerns. Even respondents who supported the status quo generally qualified their support by calling for increased oversight, clearer guidance and improved consistency across testing laboratories. Although the TGA agrees the *in vivo* testing remains the most established method for assessing sunscreen performance, the TGA recognises that there are significant variability concerns which are fundamental to the method itself.

Mandating *in vitro* SPF testing only, where appropriate, attracted support from respondents who prioritised standardisation, reproducibility and ethical considerations associated with reducing reliance on human

testing. The TGA agrees with respondents who considered that a single mandated *in vitro* approach could improve consistency in SPF claims and enable more frequent lifecycle testing. However, the TGA does not consider that the consultation feedback supports an immediate mandate for *in vitro* testing across all products and claims. Respondents consistently raised concerns that *in vitro* methods are not yet established for all formulation types or claims, particularly water resistance, and that comparability with existing *in vivo* test results remains an important consideration. Implementation challenges, including laboratory capacity, transition timing and the need for clear guidance, would also need to be addressed before any broader mandate could be considered.

The TGA notes enabling sponsors to comply with either *in vitro* or *in vivo* testing where appropriate received the most consistent support across respondent groups and was generally viewed as a balanced and pragmatic approach. Respondents considered that a framework allowing both *in vivo* and *in vitro* methods, depending on the product and claim, would provide flexibility across formulation types while supporting the progressive adoption of emerging methodologies.

The TGA considers that a staged hybrid framework is the most appropriate basis for further consideration, as it would allow validated *in vitro* methods to be adopted where suitable while retaining *in vivo* testing where it remains necessary, including for water resistance claims or product types not yet adequately addressed by *in vitro* methods. The consultation feedback also indicates that any hybrid framework would need clear regulatory expectations on method selection, acceptable variability, statistical interpretation and the management of divergent results across methods.

The TGA acknowledges that submissions did not present a simple division between the 3 options. Many respondents supported a staged or hybrid approach in which *in vitro* methods are adopted progressively as they are validated, alongside continued use of *in vivo* methods where necessary. This aligns with the TGA's view that the testing framework should reflect both current scientific validation and improved reproducibility with practical readiness.

The TGA considers that improving confidence in SPF claims will require more than a change in test method. Consultation feedback indicates that laboratory competence, data quality, transparency and regulatory clarity are central to testing reliability, regardless of whether a product is tested using *in vivo*, *in vitro* or a combination of methods. The TGA will address these matters through the other proposals in the consultation.

On balance, the TGA considers that further reform should focus on a flexible, evidence-based and staged approach that enables validated alternative *in vitro* methods to be adopted as they become scientifically and practically suitable. It allows products to be tested with a potentially more reproducible, and therefore reliable, test method. It also provides an avenue to reduce exposing human subjects to UV radiation. This approach best reflects the responses presented through consultation and provides a pathway to improve the reliability and credibility of SPF claims without mandating methods beyond their current validated scope.

TGA Proposed Reform

Option 2: Enable sponsors to comply with either *in vitro* or *in vivo* testing where appropriate

The TGA considers that option 2 is the preferred basis for reform to improve reproducibility of SPF testing. The framework will recognise the evolution of the test methods and consider the suitability of the tests for specific products and claims.

Consultation matter 1B: Limited regulatory oversight for laboratories performing SPF testing

The TGA does not regulate or accredit testing facilities, so the onus of responsibility for selecting an appropriate laboratory rests with the sponsor. The TGA does not have oversight of which testing laboratory a sponsor has used, or the rigour of the testing conducted. However, the sponsor must provide this information to the TGA if the TGA requests it under the provisions of the *Therapeutic Goods Act 1989* (the Act).

Options proposed to address Issue 1B

- Option 1: Status quo - maintain current level of oversight for sunscreen testing laboratories.
- Option 2: Require that SPF testing results must come from an accredited or certified laboratory.

Overall summary of stakeholder responses to matter 1B

Option 1: Status quo

Support for option 1 was largely from industry respondents with very limited support across other groups. This was based on keeping laboratory selection workable and strengthening sponsor responsibility rather than mandating a narrow accreditation pathway.

Many respondents shared the TGA's concerns around the reliability of SPF testing data and agreed that laboratory competency is important in obtaining reliable and accurate test results. However, there were significant concerns raised regarding the suitability of ISO/IEC 17025 for all available SPF testing methods, particularly *in vivo* testing, and that accreditation alone would not necessarily address fraud, poor practice or method variability. One specific concern raised was that ISO 17025 is only a general accreditation and may not address the technical requirements for SPF testing. In particular, respondents agreed that ISO 17025 accreditation may be suitable for *in vitro* SPF test methods but would not be appropriate for the alternative *in vivo* method.

Respondents also raised practical concerns with option 2, including limited availability of accredited laboratories leading to reduced access to testing services, higher costs, longer lead times and possible supply disruptions. Several respondents supporting option 1 preferred a competency-based model, whereby sponsors demonstrate the competency of SPF testing laboratories. It is suggested that this could occur through a combination of proficiency testing, independent technical audits, internal quality controls, and adherence to regulatory guidance. These respondents generally accepted the need for better assurance but favoured a more flexible pathway that would not limit the available testing laboratories.

Option 2: Require that SPF testing results must come from an accredited or certified laboratory

Option 2 received broad levels of support across groups, with strongest support from consumers, health professionals and academia and moderate support from industry and those with no stated affiliation. Support was generally based on the view that requiring testing laboratories to be accredited or certified would improve the reliability of SPF testing, strengthen laboratory oversight, restore confidence in sunscreen claims and enhance public health outcomes.

Across these groups, respondents emphasised the need to ensure that labelled SPF reflects actual protection, highlighting risks to consumer safety and public health where testing is unreliable. Responses also identified limitations in current arrangements, including insufficient assurance of laboratory competence, variability in testing and gaps in regulatory oversight.

Accreditation or certification to recognised standards was therefore seen as necessary to improve consistency, strengthen data integrity and rebuild trust in sunscreen testing and labelling. Some respondents acknowledged potential impacts on cost, laboratory testing capacity and implementation timelines, these

were generally considered secondary to the need for stronger assurance of laboratory competence and greater regulatory oversight.

Industry responses were broadly aligned with other stakeholder groups in supporting option 2. However, industry submissions placed greater emphasis on additional implementation risks, including global alignment and potential impacts on product availability. They also highlighted system-level integrity issues such as testing variability, product substitution and the need for ongoing verification mechanisms beyond accreditation alone.

TGA response to matter 1B

The TGA considers that consultation feedback demonstrates a clear need to strengthen confidence in SPF testing outcomes, while recognising differing views on the most appropriate approach to laboratory oversight. The feedback shows broad agreement that current arrangements do not provide sufficient assurance of testing reliability; however, respondents differed on whether this should be addressed through strengthened oversight of the existing framework or through the introduction of mandatory accreditation or certification requirements.

The TGA considers that maintaining the current framework without further regulatory action would not adequately address stakeholder concerns. While some respondents supported retaining flexibility in laboratory selection, this support was generally qualified by calls for clearer expectations, stronger oversight and improved consistency across testing laboratories. Consultation feedback indicates that sponsor-led assurance alone is unlikely to provide sufficient confidence in SPF claims.

Mandating that SPF testing be conducted by accredited or certified laboratories attracted support from respondents who prioritised reliability, reproducibility and public confidence in SPF claims. The TGA agrees that independent assessment of laboratory competence has an important role in improving confidence in SPF claims. Accreditation, certification or equivalent independent assurance mechanisms could support more consistent laboratory practice, improve transparency and provide greater confidence that SPF testing is conducted to an appropriate standard.

However, the TGA does not consider that an immediate, uniform accreditation requirement is appropriate at this time. The TGA also does not accept that requiring independent assurance of laboratory competence would represent a departure from international norms. ISO/IEC 17025 is an internationally recognised framework for demonstrating the competence of testing laboratories and is used across a wide range of laboratory disciplines, including complex biological, microbiological and biochemical assays. The fact that SPF testing involves biological variability does not, of itself, make accreditation unsuitable or inconsistent with established laboratory practice.

The TGA acknowledges that respondents raised concerns about cost and access to testing services. However, the TGA considers that these concerns should be assessed in proportion to the overall cost of product development, claim substantiation and market entry. Accreditation or equivalent independent assurance may increase some testing costs, but the TGA does not consider that this should be prohibitive or that it would necessarily have a significant impact on the overall cost of SPF testing when weighed against the public health importance of reliable SPF claims.

The TGA's view is that reform should proceed through a phased approach. This should strengthen assurance of laboratory competence and testing quality while recognising differences between SPF testing methods and preserving practical access to testing services. A phased approach would allow regulatory requirements to be aligned with laboratory readiness, available accreditation pathways and the broader transition toward validated alternative test methods, without accepting cost or implementation concerns as reasons to avoid stronger oversight.

The TGA considers that accreditation alone will not resolve all issues contributing to variability in SPF claims. Any strengthened framework should also include clearer regulatory expectations for method application, data integrity, record keeping, management of variability and the use of proficiency testing, targeted audits or other assurance tools where appropriate.

On balance, the TGA supports stronger oversight of SPF testing laboratories through a phased approach rather than an immediate blanket accreditation mandate. This position recognises practical implementation issues but does not accept that strengthened laboratory assurance is inconsistent with international practice, technically unsuitable for biological testing, or likely to impose prohibitive costs. The approach best addresses the concerns raised through consultation, improves confidence in SPF testing outcomes and supports a proportionate pathway to more reliable SPF claims.

TGA Recommendation for Reform

Option 2: Require that SPF testing results must come from an accredited or certified laboratory - with a phased approach

The TGA considers that option 2, implemented through a phased approach, is the preferred basis for reform to improve regulatory oversight of testing laboratories. This approach would align with the tiered laboratory model described on the TGA website, bringing clearer requirements for laboratory competence, quality systems and testing assurance. It would also allow requirements to be introduced in stages, recognising the maturity of available accreditation pathways, the evolution of SPF test methods, and the suitability of particular methods for specific products and claims.

Consultation matter 1C: Lack of flexibility to accommodate new testing requirements for sunscreens in a timely manner

There is significant variability in results obtained using the current *in vivo* (human) testing method in ISO 24444, and this variability increases with the SPF value. *In vivo* SPF testing is the current mandatory testing required for sunscreens. However, there are new recently published ISO methods that offer an alternative to *in vivo* testing.

Options proposed to address Issue 1C

- Option 1: Status quo - maintain the current approach of adopting AS/NZS 2604 into therapeutic goods legislation.
- Option 2: Directly reference AS/NZS 2604 in new instrument for sunscreen testing requirements.
- Option 3: Directly reference international ISO standards in a new instrument for sunscreen testing requirements.

Overall summary of stakeholder responses to matter 1C

Option 1: Status quo

Support for Option 1 was limited.

Industry respondents supporting the status quo considered that current sunscreen concerns appear to relate to compliance, laboratory practices and application of test methods and regulatory oversight, rather than the test methods themselves. One submission engaged with the consultation paper's rationale for reform, supporting both the status quo and directly referencing AS/NZS 2604, but questioned whether a new instrument would be the most appropriate mechanism to strengthen or introduce additional requirements.

International industry support was linked to preserving Australia-New Zealand harmonisation and avoiding disruption to domestic and trans-Tasman supply chains, supporting both the status quo and directly referencing AS/NZS 2604.

Option 2: Directly reference AS/NZS 2604 in new instrument for sunscreen testing requirements.

Option 2 was generally viewed as a balanced or pragmatic approach. Respondents supporting this option considered that directly referencing AS/NZS 2604 in a new instrument would improve the timeliness and flexibility of adopting sunscreen testing requirements, while retaining the benefits of the existing AS/NZS 2604 framework. This included local regulatory control, maintaining domestic technical and industry input, supporting trans-Tasman alignment, and enabling international methodologies to be adapted to Australian conditions.

Industry (domestic and international), health professionals, and academic respondents commonly thought option 2 would address delays in legislative adoption and commonly emphasised that AS/NZS 2604 provides an important framework for consumer protection and regulatory certainty, particularly given Australia's unique UV environment, high incidence of skin cancer, and the classification of sunscreens as a therapeutic good.

Support for option 2 was often comparative and cited concerns included that direct adoption of ISO standards (option 3) could lead to reduced domestic influence and tailoring to Australian conditions, reduced Australian-specific safeguards, increased compliance complexity, and misalignment with New Zealand. Some submissions also noted uncertainty regarding how new or emerging methods would be validated and implemented.

Option 3: Directly reference international ISO standards in a new instrument for sunscreen testing requirements.

Option 3 received substantial support from respondents (industry, consumers, professionals, academics, authorities and not stated) prioritising regulatory agility, faster adoption of updated scientific and technical developments, and closer alignment with internationally recognised standards developed through international expert consensus.

Some supporters also considered that direct ISO referencing could improve consumer protection and confidence in SPF claims, reduce double testing, support export competitiveness, improve clarity of testing requirements for manufacturers and testing facilities, and enable the TGA to respond more quickly to emerging safety, quality or efficacy concerns.

However, support for option 3 was commonly qualified by the need for further detail and assurance on implementation requirements, ongoing consultation and Australian-specific considerations. Stakeholders sought clear specification of applicable standards, appropriate transitional arrangements, and technical guidance to support consistent implementation. Several submissions emphasised that directly referencing an ISO does not preclude the ongoing role of AS/NZS 2604, Standards Australia or local expertise. There was a general emphasis on the importance for Australian-specific requirements, including water-resistance claims and suitability for Australia's high UV environment, with some highlighting a desire for greater Australian involvement in international standards development to help ensure these considerations are reflected. Stakeholders also noted the importance of avoiding divergence between therapeutic and cosmetic sunscreen requirements and managing trans-Tasman alignment.

Hybrid/no option selected

A number of respondents, predominantly authorities and some industry respondents, did not select a single option as proposed, but favoured a hybrid approach that drew elements from options 2 and 3. These views generally supported improving responsiveness and enabling more timely adoption of appropriate ISO methods, while retaining local expertise, domestic input to tailor Australian-specific requirements and trans-Tasman alignment. Suggestions included referencing both AS/NZS 2604 and other equivalent or relevant ISO standards in a new instrument or adopting a principles-based instrument, supported by guidance, that identifies applicable or acceptable standards.

Respondents cautioned against automatic adoption of ISO standards without due consideration of Australia's high UV environment, water-resistance requirements, labelling arrangements, role of CS-042 and other domestic technical expertise and Australia's classification of sunscreens as therapeutic goods.

Overall summary

Overall, stakeholders broadly supported reform to improve the timeliness and flexibility of adopting new sunscreen testing requirements but differed on the preferred approach. Option 2 was seen as a balanced approach and generally supported by respondents who prioritised continuity, retaining AS/NZS 2604 and Australian-specific safeguards, regulatory sovereignty and Australia-New Zealand alignment. Option 3 received strong support from respondents prioritising speed, international alignment, scientific currency, and the TGA's ability to respond independently to emerging public health concerns. Hybrid views suggest there may be support for an approach that combines faster adoption of appropriate ISO methods with continued domestic technical input, Australian-specific safeguards, and mechanisms to preserve trans-Tasman alignment where appropriate.

TGA response to matter 1C

The TGA acknowledges that stakeholders broadly supported reform to improve the timeliness and flexibility of adopting sunscreen testing requirements, with differing views on the preferred approach.

Stakeholder views on the proposed options were generally consistent with the considerations outlined in the consultation paper. In particular, support for retaining AS/NZS 2604, either through the current framework or through direct reference in a new instrument, was generally based on the value of established local standards processes, domestic input and expertise to adapt international methods to Australian conditions, and alignment with New Zealand. By contrast, support for directly referencing international ISO standards was generally based on reducing regulatory lag, improving access to updated testing methods, and enabling the TGA to respond more quickly to emerging scientific evidence and public health considerations.

The TGA acknowledges the importance of AS/NZS 2604 in the existing sunscreen regulatory framework. The standard provides a familiar and established framework for sponsors, manufacturers and testing laboratories, and supports alignment with New Zealand. Several respondents also considered AS/NZS 2604 enables local technical input to adapt international standards to Australia's high-UV environment. The TGA also notes concerns that direct adoption of ISO standards without adequate consideration could reduce domestic influence, create regulatory divergence, or fail to fully account for Australian-specific requirements.

At the same time, many respondents considered the existing process is not sufficiently agile for a product category with significant public health relevance and high consumer reliance. This was particularly emphasised by respondents supporting option 3, who considered that direct reference to validated ISO standards could enable more timely adoption of updated methods, improve confidence in SPF claims, and support international alignment.

The TGA also notes that submissions did not present a simple division between options 2 and 3. A number of respondents selecting option 2 supported more efficient adoption of testing requirements, while a number of respondents who selected option 3 considered Standards Australia, AS/NZS 2604 and domestic technical expertise should continue to play an important role. Some respondents also highlighted greater Australian participation in the development of ISO standards, to help ensure Australian-specific conditions are appropriately considered. Some submissions also supported a hybrid or staged approach that combines elements of options 2 and 3 as they favoured improving responsiveness while retaining local safeguards via the Joint Technical Committee, Australian-specific requirements and consideration of New Zealand alignment.

The TGA considers that these views identify an importance distinction between the source of a technical method and the regulatory mechanism used to adopt and apply it. International ISO standards may provide scientifically developed and internationally recognised testing methods; however, the regulatory framework must determine when and how those methods apply in Australia, how they interact with existing AS/NZS 2604 requirements, and whether additional Australian-specific requirements are needed. This includes consideration of water-resistance claims, labelling requirements, suitability for Australia's UV environment and Australia's classification of sunscreens as therapeutic goods.

The TGA acknowledges respondent concerns that current sunscreen issues may also involve compliance, oversight, laboratory practices and application of test methods, rather than the adoption pathway alone. These matters remain relevant to the broader regulatory response. However, they do not remove the need to consider whether the legislative mechanism for adopting sunscreen testing requirements is sufficiently

responsive. A more agile adoption pathway would not replace the need for compliance and enforcement activity but may help ensure that regulatory requirements can keep pace with validated scientific and technical developments.

The TGA also agrees that any new approach would require clear implementation arrangements. Submissions consistently emphasised the need for transparency about which standards apply, the circumstances in which they apply, how conflicts or overlaps between ISO standards and AS/NZS 2604 would be managed, and what transition periods would be provided. The TGA notes that consultation, technical guidance and proportionate transition arrangements would be important to support sponsors, manufacturers, testing laboratories and regulators, and to minimise unintended impacts on product availability, compliance certainty and trans-Tasman alignment.

Taken together, the consultation supports reform to enable a more responsive adoption of sunscreen testing requirements, while also indicating that stakeholder confidence depends on retaining appropriate safeguards. The TGA considers that the preferred reform pathway would enable faster adoption of suitable, validated testing methods while preserving the ability to apply Australian-specific requirements and draw on domestic technical expertise. This approach would recognise the public health importance of sunscreens, the need for timely regulatory action, and importance of maintaining confidence in the quality, safety and efficacy of sunscreen products supplied in Australia.

The TGA will further consider the design of a dedicated legislative mechanism for sunscreen testing requirements, including whether and how AS/NZS 2604, relevant ISO standards and any Australian-specific requirements should be referenced. Further consultation may be required on the structure of any instrument, the role of the Joint Technical Committee and Standards Australia, transition arrangements, and how alignment with New Zealand can be maintained.

TGA Proposed Reform

Option 3: Directly reference international ISO standards in a new instrument for sunscreen testing requirements - *with modifications*.

The TGA considers that option 3, with modifications and further consultation, is the preferred basis for reform. Noting considerations of Australian-specific requirements, drawing on domestic technical expertise and trans-Tasman alignment.

Consultation matter 1D: Sponsor evidence to support SPF claims is generally based on the base formula and not the final finished product

Currently, the TGA permits SPF testing to be conducted during the 'product development' phase, often on pilot batches, rather than requiring ongoing testing of commercially released batches. Due to a lack of clarity as to legal requirements, some sponsors rely on SPF testing conducted on a base formulation, rather than the final marketed formulation that includes all excipients. In some instances, this involves the sponsor SPF testing a representative formulation and providing a justification for why the results can be extrapolated to a particular sunscreen included in the Australian Register of Therapeutic Goods (ARTG). After a product's formulation is scaled up for commercial manufacturing, sponsors typically do not retest the SPF performance of the final, market-ready batches.

Options proposed to address Issue 1D

- Option 1: Status quo.
- Option 2: Keep testing requirements for base formulations with guidance to sponsors on when additional product testing is advised.

- Option 3: Mandate SPF testing at the time of listing on the finished product and periodically while the product is in the ARTG including over the shelf life of the product.

Overall summary of stakeholder responses to matter 1D

Option 1 Status quo

Support for option 1, maintaining the status quo, was largely limited to industry respondents. Support was based on the view that the current framework is appropriate for listed medicines and aligned with existing regulatory practice, while allowing the scientific judgement and flexibility needed for product development.

Respondents supporting option 1 raised concerns that options 2 and 3 would introduce increased regulatory burden, costs and pressure on limited testing capacity, without clear evidence of additional benefit. They considered SPF performance to be adequately controlled through GMP and stability programs monitoring active ingredients.

There was minimal support for option 1 from consumers, professional bodies, academia and authorities. These groups generally considered that the status quo does not sufficiently address concerns regarding confidence in labelled SPF performance or provide adequate regulatory oversight of products available on the market.

Option 2: Keep testing requirements for base formulations with guidance to sponsors on when additional product testing is advised.

Option 2 was generally supported as a proportionate middle-ground that could improve/strengthen regulatory oversight without requiring mandatory finished product testing. This was primarily from industry with some/limited support spread across other respondent groups.

Support was based on the view that base formulation testing remained appropriate where it is representative of the finished product, provided there is clear regulatory guidance regarding formulation changes and additional testing to ensure consistency and support decision making.

Option 2 was often preferred due to concerns that option 3 would increase costs, deviate from current regulatory practice and create additional regulatory burden without clear additional benefit. These concerns would lead to potential flow-on effects for laboratory testing capacity, product availability and on-going formulation improvements.

Option 3: Mandate SPF testing at the time of listing on the finished product and periodically while the product is in the ARTG including over the shelf life of the product.

Option 3 was strongly supported across most respondent groups including consumers, health professionals, academia, authorities, domestic industry and those with no stated affiliation. This was based on the view that testing the finished product provides the most direct assurance that the labelled SPF reflects the product used in practice. Support was generally framed around public health and maximising consumer safety and ensuring confidence in sunscreen performance.

Some of the support for option 3 was conditional on implementation considerations, including testing capacity, cost and clear guidance. This included use of *in vitro* testing methods for ethical reasons, reduced time and testing costs as well as clear guidance for acceptable levels of variability.

TGA response to matter 1D

The consultation feedback demonstrates a clear need to strengthen assurance that labelled SPF values reflect the performance of the finished product supplied to consumers over the product lifecycle. While stakeholders expressed differing views on the most appropriate mechanism to achieve this, there was broad agreement that confidence in SPF claims requires more consistent and transparent verification than is currently provided.

The TGA assessment is that maintaining the status quo would not adequately address these concerns. Although some respondents supported reliance on base formulation testing supported by GMP and stability programs, this position was generally qualified by requests for clearer guidance on formulation changes, testing expectations and acceptable variability. Consultation feedback also indicates that existing approaches may not fully ensure that SPF claims remain representative where products are scaled up, modified or maintained over time without further verification.

The TGA notes that moderate support was given to keeping current testing requirements for base formulations with guidance to sponsors on when to conduct additional product testing which was generally viewed as a balanced and pragmatic approach. Respondents supporting this option considered that retention of base formulation testing, supported by clearer regulatory guidance, could improve consistency without introducing significant additional burden. The TGA agrees that clearer expectations are required, particularly in relation to triggers for retesting, interpretation of variability and evidence to support SPF claims. However, the TGA considers that reliance on base formulation testing alone, even with strengthened guidance, may not fully address whether the tested product remains representative of the product supplied to consumers over time.

Mandating SPF testing at the time of listing on the finished product and periodically while the product is in the ARTG including over the shelf life of the product, received stronger support from consumers, professional groups, academia and authorities, particularly where respondents prioritised consumer protection, public confidence and direct verification of SPF claims. The TGA acknowledges that testing of the finished product provides the most direct assurance that the labelled SPF reflects the product supplied to and used by consumers. Respondents supporting this option also highlighted the role of periodic or lifecycle testing in strengthening confidence in SPF claims, improving accountability and supporting regulatory oversight.

However, the TGA notes that support for option 3 was commonly conditional on implementation considerations. This included testing capacity, cost, impacts on product development timelines and the need for clear regulatory guidance on testing frequency, acceptable variability and interpretation of results. Respondents also raised concerns regarding the feasibility of mandatory testing at specific lifecycle stages, particularly where existing stability and GMP controls are relied upon to demonstrate product consistency.

The TGA acknowledges that consultation feedback did not present a simple division between the options. Many respondents supported elements of both options 2 and 3, including approaches where base formulation testing is complemented by targeted finished-product testing or risk-based lifecycle verification. This indicates support for a more structured and transparent framework for SPF evidence, rather than reliance on sponsor judgement alone or prescriptive testing in all circumstances.

The TGA considers that improving confidence in SPF claims requires clearer regulatory expectations across the product lifecycle. This includes clarification on when testing of the finished product is required, how often verification should occur, what constitutes a significant formulation change, and how variability in SPF results should be interpreted. These issues are closely linked to broader concerns identified in the consultation, including testing variability, laboratory oversight and the need for strengthened post-market assurance.

On balance, the TGA considers that the preferred approach is to strengthen confidence that labelled SPF claims accurately reflect the performance of sunscreen products supplied to consumers by requiring direct verification of the finished product. SPF testing on the finished product at the time of listing, supported by appropriate periodic verification over the product lifecycle, would provide more direct and transparent evidence that products continue to meet their claimed level of protection. This approach would better address concerns raised through consultation about the representativeness of base formulation testing alone, particularly where products are scaled up, reformulated, transferred between manufacturing sites or maintained on the ARTG over time.

The TGA therefore supports further consideration of a reform pathway that places greater emphasis on finished-product verification, implemented in a proportionate and risk-based manner. This would allow regulatory requirements to focus on circumstances where finished-product testing is most important, while taking account of stakeholder concerns about testing capacity, cost and implementation timeframes. Clear guidance on testing frequency, acceptable variability, significant formulation changes and lifecycle verification would be essential to support sponsors and laboratories and to ensure that strengthened requirements deliver practical, consistent and meaningful assurance of SPF claims.

TGA Proposed Reform

Option 3: Mandate SPF testing at the time of listing on the finished product and periodically while the product is in the ARTG including over the shelf life of the product.

The TGA considers that option 3 is the preferred basis for reform to strengthen assurance that SPF claims are supported by evidence representative of the product supplied to consumers, are accurate at market entry and remain reliable over time. The framework will require verification of SPF performance on the finished product at appropriate points, including at listing and across the product lifecycle, implemented in a proportionate and risk-based manner.

Consultation matter 1E: Sponsors are not required to make their SPF testing data available to the TGA at the time of listing or publicly available to consumers

Sponsors of sunscreen products are not required to provide their SPF testing data to the TGA at the time of listing. While sponsors must hold evidence to support their SPF claims and provide it to the TGA if required, there is no obligation for this information to be submitted proactively or included in the ARTG entry. Further, there are no requirements for sponsors to make their SPF testing data publicly available, meaning that both the regulator and consumers have limited transparency regarding the evidence underpinning SPF claims on sunscreen products.

Options proposed to address Issue 1E

- Option 1: Status quo
- Option 2: Require sponsors to provide testing data to the TGA at the time of listing, which will be held in confidence
- Option 3: Require sponsors to make their testing data publicly available.

Overall summary of stakeholder responses to matter 1E

Option 1: Status quo

Support for option 1 (status quo) was generally framed around the current listed medicines framework. Consumer respondents questioned whether introducing additional sunscreen-specific requirements would be appropriate or justified in the absence of a clear benefit, while industry (domestic and international) respondents supported the status quo as maintaining the existing listing arrangements. Additionally, consumers considered that options 2 and 3 would not necessarily improve regulatory assurance, while industry emphasised that sponsors are already required to hold SPF evidence and that the TGA can request this information post-market.

Domestic and international industry respondents expressed conditional support for option 2 if SPF data was held confidentially and did not delay listing, although they questioned its purpose, practicality and value if the data would not be reviewed or approved at the time of listing. Domestic industry respondents further noted concerns relating to increased regulatory burden, TGA resourcing requirements, potential difficulties in verifying report authenticity and reconciling listed products with syndicated testing.

Respondents supporting option 1 cited concerns about public disclosure (option 3), including limited consumer value and interpretability, potential for misuse or misleading comparisons, disclosure of commercially sensitive information, possible impacts on public confidence in sunscreens, and potential to incentivise a 'race' to higher SPF values or use of less rigorous laboratories without improving real-world consumer protection.

Domestic industry and consumer respondents suggested that regulatory effect may be better directed towards strengthening oversight of SPF testing, including laboratory accreditation, improved consistency of SPF reports and increasing targeted post-market compliance checks.

Option 2: Require sponsors to provide testing data to the TGA at the time of listing, which will be held in confidence.

Option 2 received the strongest support across all respondent types (consumers, industry, professionals, academia, authorities, other and not stated) as a proportionate way to strengthen regulatory oversight while avoiding the risks associated with full public disclosure.

Respondents commonly considered that confidential submission of SPF testing data to the TGA at listing would improve visibility of testing practices, support regulatory verification and compliance monitoring, increase sponsor accountability, and improve assurance of SPF claims; addressing the current limitations of the regulatory framework.

Some respondents expected TGA to actively use submitted data for review, auditing, monitoring, enforcement and early issue detection, while others' support was conditional on greater clarity about how the data would be used in practice (i.e. routinely assessed or simply held). More broadly, respondents raised implementation concerns, including the need for adequate resourcing and IT capability, and no material delays to the listing process.

Respondents also suggested calibrated implementation approaches to balance improved regulatory assurance with administrative efficiency and confidentiality. These included mandatory submission at listing supported by targeted or random audits, rather than routine review of every submission; risk-based submission for identified higher-risk cases instead of universal pre-market submission for all listed sunscreens; and limited summary-level disclosure or targeted sharing to improve public assurance and transparency without requiring full public disclosure of technical reports.

Respondents consistently opposed full public disclosure (option 3) due to commercial sensitivity and intellectual property risks, potential misinterpretation of technical SPF reports and the risk of distorting consumer behaviour and decision-making regarding sunscreen use.

Option 3: Require sponsors to make their testing data publicly available.

Option 3 was generally supported by respondents (consumers, professionals, domestic industry and other) who considered public disclosure would strengthen transparency, accountability and confidence in sunscreen claims. Support was linked to enabling independent verification of SPF claims and deterring poor-quality or fraudulent testing or sub-standard formulations. Respondents also considered that greater transparency could improve reliability of SPF claims, support informed decision-making, restore or strengthen consumer trust, and contribute to public health outcomes.

Some respondents suggested that public disclosure should be presented in accessible formats and calibrated to protect commercially sensitive or proprietary information.

Hybrid/no option selected

Respondents who did not select a single option supported a combined or calibrated approach.

Domestic industry respondents conditionally supported option 2 where the purpose and use of submitted SPF data is clear and the TGA uses it for proactive monitoring and issue detection. Otherwise, option 2 may create unnecessary regulatory burden and costs and option 1 would be preferred. Concerns were also raised about resourcing, increased costs, and impacts on the existing listing framework and opposed option 3 due to concerns regarding limited consumer ability to interpret technical data, commercial sensitivity and risks of broader regulatory disclosure precedents.

Consumer respondents favoured a stronger TGA role in verification and some suggested a hybrid approach that combined options 2 and 3 will enhance regulatory oversight and transparency, improve accountability (for sponsors and the TGA), enable independent scrutiny of test results and better protect consumers.

TGA response to matter 1E

The TGA acknowledges that stakeholders expressed a range of views on whether additional requirements relating to the submission or disclosure of SPF testing data are needed to strengthen assurance of SPF claims for listed therapeutic sunscreens.

Overall, stakeholder feedback indicated a preference for strengthening regulatory oversight of SPF claims, with most respondents supporting option 2 (confidential submission of SPF testing data to the TGA at the time of listing). Option 3 (public disclosure) was not supported by the majority of respondents, and option 1 (status quo) received limited support.

The TGA notes that support for option 1 (status quo) was limited and generally reflected views that additional sunscreen-specific requirements may not provide a clear regulatory benefit and would depart from the existing listed medicines framework, including its reliance on sponsor certification that evidence is held and available to the TGA on request through post-market compliance activities. Some respondents also considered that issues relating to SPF testing may be better addressed through strengthened oversight of testing practices and laboratories, including laboratory accreditation, improved consistency of SPF reports and increased targeted post-market compliance activities.

The TGA acknowledges stakeholder views that concerns about the reliability of SPF testing may be addressed, in part, through strengthened oversight of testing laboratories, including laboratory accreditation considered under other proposals in this consultation. The TGA considers these reforms to be related and complementary. Laboratory oversight may improve confidence in the quality and consistency of SPF testing, while submission of SPF testing data at the time of listing may improve the TGA's visibility of product-specific evidence. Under the current model, sponsors are not required to submit SPF testing data to the TGA at the time of listing or make this information publicly available to consumers. The TGA considers this may limit its ability to proactively identify product-specific issues and respond early to emerging risks.

The TGA notes that option 2 received the strongest support across all respondent types. Stakeholders generally considered that mandatory submission of SPF testing data at the time of listing would be a proportionate approach to improve regulatory visibility of testing practices and facilities, support verification of testing data and compliance monitoring, increase sponsor accountability, and provide greater assurance in the reliability of SPF claims while avoiding the risks associated with full public disclosure. However, support was often conditional. Several stakeholders sought clarity on the purpose and use of submitted data, with some expecting that the TGA would actively use the data for review, auditing, monitoring, enforcement and early issue detection. Conditional support was also expressed subject to assurance that listing timeframes would not be affected.

The TGA clarifies that the intent of option 2 is to require submission of SPF testing data at the time of listing to enable verification that evidence was held at that time and to support risk-based compliance and post-market review activities where needed. The TGA does not intend to undertake routine pre-market evaluation of SPF testing data under this option, and as stated in the consultation paper, listing timeframes would not be impacted.

The TGA also notes implementation considerations and concerns raised, which included resourcing, IT system capability, administrative burden and potentially increased costs.

The TGA acknowledges these considerations and concerns and notes that, if adopted, option 2 would be designed to support a risk-based and proportionate regulatory approach, supported by appropriate system capability and clear guidance.

The TGA notes that the majority of respondents did not support option 3 (public disclosure of SPF testing data), citing concerns regarding commercial sensitivity, intellectual property risks, limited consumer value, and potential for misinterpretation of technical data, with possible unintended impacts on consumer behaviour and confidence in sunscreens.

At the same time, a minority of stakeholders supported option 3 as a means of improving transparency, accountability and enabling independent scrutiny of SPF claims. The TGA acknowledges these perspectives

and notes that any approach to disclosure would need to ensure information is meaningful, accessible, and appropriately balanced against commercial considerations.

A number of stakeholders proposed calibrated or hybrid approaches, drawing on elements of options 2 and 3 to enhance regulatory oversight and transparency while supporting administrative efficiency, confidentiality and accessibility. These included mandatory submission at the time of listing supported by targeted or random audits rather than routine review of every submission; risk-based submission for identified higher-risk cases rather than universal pre-market submission; and limited summary-level disclosure or targeted sharing to improve public assurance without requiring full public disclosure of technical SPF test reports. The TGA considers that these views provide useful insight into how regulatory assurance and transparency objectives could be balanced.

In considering the feedback received, the TGA will further assess options to strengthen regulatory assurance of SPF claims in a manner that is proportionate, risk-based and consistent with the listed medicines framework. This includes considering mechanisms to improve regulatory visibility of SPF evidence, support proactive compliance and monitoring activities, and maintain appropriate protections for commercially sensitive information, while avoiding unnecessary regulatory burden.

TGA Proposed Reform

Option 2: Require sponsors to provide testing data to the TGA at the time of listing, which will be held in confidence - *with modifications*.

The TGA considers that option 2, with modifications and further consultation, is the preferred basis for reform. Noting considerations of system and resourcing requirements, alignment with related reforms to strengthen oversight of SPF testing laboratories and summary-level disclosure.

Consultation matter 2: Potential efficacy or quality issues with specific formulations/ingredients

There is a lack of appropriate and robust quality standards for sunscreens, including the absence of legislation comprehensively addressing ingredient-level properties, finished product formulation requirements and performance considerations.

Options proposed to address Issue 2

- Option 1: Status quo – maintain current oversight of sunscreen ingredients and formulations.
- Option 2: Develop an instrument for ingredient quality requirements to ensure efficacy.
- Option 3: Require pre-market evaluation for safety, quality and efficacy for all sunscreens (e.g. a registered products model).

Overall summary of stakeholder responses to matter 2

Option 1: Status quo

Support for Option 1 came predominantly from industry stakeholders. International agencies also supported the option, and a smaller number of submissions were received from general consumers.

Respondents generally supported retaining the current sunscreen regulatory framework, rather than introducing broad ingredient-level requirements or requiring all sunscreens to undergo pre-market registration.

The main justification is that the underlying problem has not been clearly defined, existing GMP and pharmacopeial controls are considered sufficient for ingredients, and recent concerns appear more closely

linked to SPF testing variability, laboratory reliability, or product-level substantiation than to raw material quality and final sunscreen product.

Respondents commonly cautioned that options 2 and 3 could increase costs, delay market access, reduce innovation in formulation and UV filters and formulation flexibility, constrain supply, and impose a disproportionate regulatory burden without clear evidence of improved public health outcomes.

Several submissions instead recommended targeted reforms, including identifying and publishing a root-cause analysis, strengthening SPF substantiation, improving laboratory accreditation, clarifying guidance, and enabling more efficient pathways for new excipients.

Option 2: Develop an instrument for ingredient quality requirements to ensure efficacy.

Support for Option 2 came from a diverse range of stakeholders. Consumer and industry stakeholders were the primary supporters of the option, while academia, health professionals, and other stakeholder groups also expressed support.

Respondents supported introducing clearer ingredient-level quality requirements or guidance to improve sunscreen efficacy while maintaining a proportionate regulatory approach. The main rationale behind the selection of selecting option 2 is that better control of UV filter attributes, raw material quality, particle size/distribution, purity, stability, and formulation compatibility could improve SPF consistency and reduce variability across products and batches.

Many respondents see option 2 as a middle-ground approach: stronger than the status quo but less burdensome than full pre-market registration under option 3. In addition, this will still allow consumers to have confidence in the sunscreen.

Several submissions emphasise that any new standards should be risk-based, targeted, consistently applied across relevant UV filters, developed with industry input, supported by clear guidance, and implemented with staged transition arrangements to avoid supply disruption or unnecessary market exits.

Option 3: Require pre-market evaluation for safety, quality and efficacy for all sunscreens (e.g. a registered products model).

Support for Option 3 was primarily expressed by consumer respondents. Industry respondents and health professionals also supported the option, while support among international industry and agency respondents was more limited.

Respondents who supported option 3 generally favoured stronger pre-market evaluation of sunscreens, including TGA assessment of safety, quality and efficacy before products are supplied. The main grounds for supporting this option were that the current “list first, check later” model was considered insufficient for products that are used widely and frequently, including products for children. Supporters considered that sponsors should provide robust evidence before market authorisation is granted. Common concerns included the safety of chemical sunscreen filters, including references to 4-Methylbenzylidene camphor (4-MBC), homosalate and other filters, and the need to prevent products with inadequate substantiation or potentially harmful ingredients from reaching consumers. Overall, supporters considered that option 3 could improve public trust, restore consumer confidence, reduce reliance on poor-quality or fraudulent data, and align sunscreen safety claims with stronger evidence-based regulatory oversight.

No option selected

Some respondents did not express a clear preference for any of the three options. These respondents either did not answer the question directly or explicitly indicated that they were not taking a position.

However, several substantive comments were provided. These respondents generally considered that the problem and rationale for reform had not been defined clearly enough to support a specific option, particularly in the absence of TGA findings or a root-cause analysis. Some acknowledged that regulatory change may be required but viewed the consultation as an early step that should be supported by further evidence, assessment of options against identified root causes, and more detailed implementation planning. Overall, this group expressed a cautious position, recommending that any reform should be targeted,

proportionate and workable before a broad regulatory option is adopted. Consumers were the largest stakeholder group selecting "No option selected", followed by industry respondents.

Overall summary

Overall, respondent views were relatively evenly distributed across the 3 proposed regulatory options, with no single option receiving majority support. Support for each option was received from a range of stakeholder groups, and a number of respondents did not indicate a preferred option. Major stakeholder categories, particularly industry and consumer respondents, also appeared to show broadly consistent preferences within their respective groups.

Industry and international stakeholders showed the strongest support for option 1, favouring retention of the current regulatory framework. The main rationale was that the underlying problem has not been clearly defined, existing GMP and pharmacopeial controls are considered sufficient for ingredients, and more intensive regulation could increase costs, delay market access, reduce innovation and disrupt supply without clear evidence of improved public health outcomes.

The largest number of option 2 selections came from consumer respondents, followed by industry respondents. Proportionally, academia showed the strongest within-group support for option 2, with 4 of 7 respondents selecting this option. Support for option 2 reflected a preference for a proportionate middle-ground approach, introducing clearer ingredient-level quality requirements or guidance will improve SPF consistency and product reliability while avoiding the burden of full pre-market registration.

Support for option 3 is strongest among consumer respondents, who favour stronger pre-market assessment of sunscreen safety, quality and efficacy to improve public confidence and reduce the risk of inadequately substantiated products entering the market. The main rationale is that the current "list first, check later" model is considered insufficient for products that are widely and frequently used, including by children. Supporters consider that sponsors should provide robust evidence before market authorisation is granted, reducing the risk that products containing inadequately assessed or potentially unsafe ingredients, such as 4-Methylbenzylidene camphor (4-MBC) and homosalate, enter the market. Overall respondents consider that option 3 strengthens confidence in sunscreen use by ensuring claims and ingredients are supported by appropriate evidence before supply.

Respondents who did not select an option generally considered that further evidence, root-cause analysis and implementation planning were needed before a preferred regulatory pathway could be identified.

TGA response to matter 2

The TGA acknowledges that consultation feedback presented a range of views on whether the current regulatory framework provides sufficient assurance of the quality, safety and efficacy of sunscreen ingredients and formulations, or whether additional regulatory controls are needed to strengthen confidence in sunscreen performance. There was no clear consensus on the preferred regulatory pathway. While there was general agreement that maintaining confidence in sunscreen performance is critical, respondents differed on whether this is best achieved through existing controls, enhanced ingredient-level requirements, or a more comprehensive pre-market evaluation model.

The TGA notes that support for maintaining the current framework for sunscreen ingredients and formulations was generally linked to the view that sunscreens are low-risk listed medicines and that existing requirements already provide an appropriate level of regulatory assurance. Respondents supporting this approach also commonly noted that the underlying issues identified in the consultation were not clearly attributed to ingredient or formulation controls, and that further evidence would be required to justify significant regulatory change.

In the TGA's view, although sunscreens are listed medicines, their high level of consumer use and important role in skin cancer prevention mean that confidence in their quality, performance and claim substantiation is particularly important. Respondents supporting the status quo frequently called for improvements in areas such as SPF substantiation, laboratory oversight and regulatory guidance, indicating that additional measures may be required to strengthen overall confidence in sunscreen performance. TGA recognises that these matters will be addressed through other proposals in the consultation and as a subsequence of

reforms in these areas, may reduce the impact of concerns with specific formulations or ingredients. Yet the TGA is of the opinion that the lack of appropriate and robust quality standards for sunscreens is a contributing factor to the current concerns with lack of efficacy for some sunscreen products. The TGA considers that maintaining the current oversight of sunscreen ingredients and formulations will not fully address stakeholder concerns.

Increasing ingredient-level quality requirements attracted mixed support. Respondents supporting this approach generally considered that clearer and more consistent specifications for ingredients could improve formulation consistency and reduce variability in SPF outcomes. The TGA acknowledges these views and agrees that defining critical quality attributes may contribute to improved product performance in some cases.

However, the TGA also notes that this option raised significant concerns across respondent groups. Many respondents questioned whether tighter ingredient-level controls would directly address the primary issues identified in the consultation, particularly variability in SPF testing and laboratory performance. Concerns were also raised regarding increased regulatory burden, potential impacts on innovation, duplication with existing quality and GMP requirements, and the feasibility of implementing Australia-specific standards.

Mandating pre-market evaluation for sunscreens received support from respondents who considered that additional pre-market scrutiny could improve confidence in sunscreen claims and provide greater assurance before products are supplied. The TGA agrees that additional regulatory assurance may be warranted in some areas. However, the TGA does not consider that the consultation feedback supports adoption of a full pre-market registration model for all sunscreens at this time. Although pre-market evaluation would provide a higher level of regulatory assurance, it would represent a substantial change to the listed medicines framework and may have significant implications for regulatory burden, product availability, affordability and innovation. While sunscreens have high consumer use and an important public health role, any increase in regulatory requirements should be proportionate, fit-for-purpose and ensuring measures effectively address concerns.

On balance, the TGA considers that a risk-based approach to ingredient and formulation quality requirements is preferable to either maintaining the status quo or adopting a full pre-market evaluation model for all sunscreens. This approach would allow the TGA to strengthen assurance of sunscreen quality and performance in areas where there is evidence of need, while maintaining the benefits of the listed medicines framework. Such an approach would recognise the high level of consumer exposure to sunscreen products and their role in cancer prevention, while allowing targeted improvements supported by evidence. This would avoid unnecessary regulatory burden or unintended impacts on innovation and product availability. Consultation feedback also indicates that any changes in this area should be clearly defined, scientifically justified and aligned with international frameworks where possible.

Therefore, the TGA considers that the most appropriate next step is to further explore ingredient and formulation quality requirements where these are scientifically justified and relevant to sunscreen performance. This may include consideration of critical quality attributes that can affect SPF performance, while ensuring any requirements remain proportionate, practical and aligned with international approaches where possible.

TGA Proposed Reform

Option 2: Develop an instrument for ingredient quality requirements to ensure efficacy – *with modifications*.

The TGA considers that a modified option 2 is the preferred basis for reform to potential efficacy or quality issues with specific formulations/ingredients. This modified option will take a stepwise approach through exploration of ingredients and/or formulations relevant to sunscreen performance and where there is evidence of need, suitable quality standards will be considered and implemented.

Consultation matter 3: Labelling matter: SPF labelling considerations

Current misconceptions and understanding of SPF values, combined with the variability of test results, underscore the need for clearer labelling to ensure that consumers understand the protection a sunscreen offers and to provide sponsors greater certainty of regulatory compliance.

Options proposed to address Issue 3

- Option 1: Status quo – maintain use of current SPF rating system for labelling.
- Option 2: Provide additional labelling requirements for the SPF ratings.
- Option 3: Change labelling requirements for sunscreen performance ratings.

Overall summary of stakeholder responses to matter 3

Option 1: Status quo

Support for option 1 was generally based on the view that the current SPF numerical system is familiar, internationally recognised, and already well understood by consumers. A common argument was that retaining the existing system would preserve consistency with global markets, avoid unnecessary consumer re-education, and prevent costly relabelling or compliance burdens. Many respondents also argued that the core issue is not the labelling framework itself, but the reliability of SPF testing and claims, so changing labels would not address the underlying problem.

However, this was most strongly the view of industry (domestic and international), consumers, and many not-stated respondents. These groups tended to emphasise familiarity, simplicity, international alignment and the risk that changing the system could create confusion or undermine trust. Consumer respondents in particular said broad categories or simplified graphics could mask meaningful differences between products and reduce people's ability to compare protection levels. Industry respondents were especially concerned that Australia could become an outlier internationally and that changing the system would increase costs without clear public health benefit.

That said, professional and academic respondents who supported option 1 often added an important qualification: the SPF system may be worth retaining, but it should be supplemented by clearer UVA information and better consumer education. So even among supporters of the status quo, there was a recurring view that the current label does not communicate enough about broader sun protection.

Option 2: Provide additional labelling requirements for the SPF ratings.

Support for option 2 was generally framed as an additive or middle-ground approach. Respondents supporting this option did not want to remove SPF numbers, but considered that additional explanatory text, descriptors, or other supporting information could help consumers better understand what SPF means in practice. This included suggestions such as explanatory statements, percentage UVB filtration information, usage guidance, application and reapplication messages, and in some cases clearer UVA information. The rationale was that consumers already know the SPF system, so reform should build on that familiarity rather than replace it.

However, this view was particularly associated with consumers, authorities, academia and some international industry respondents. These groups tended to see option 2 as a practical way to improve understanding without disrupting a well-established labelling system. Authorities often focused on clearer, standardised consumer information and public health messaging, including practical instructions that affect real-world protection. Academic respondents also tended to support explanatory information that helps consumers understand diminishing returns at higher SPF levels and the fact that no sunscreen provides complete protection.

By contrast, some industry and authority respondents were cautious even about option 2, particularly where it involved percentage filtration statements or explanatory wording that might oversimplify the science or

create a false sense of security. So, while option 2 had broad appeal as a low-disruption reform, support often depended on exactly what additional information would be required and how it would be presented.

Option 3: Change labelling requirements for sunscreen performance ratings.

Support for option 3 was generally based on the view that precise SPF numbers can overstate certainty and may not reflect real-world sunscreen performance. Respondents favouring this option argued that consumers often interpret SPF values too literally, even though actual protection depends heavily on how sunscreen is applied, reapplied and used in practice. On this basis, some supported moving toward broader protection categories, dual-labelling, or other more intuitive systems that better reflect testing variability, diminishing returns at high SPF levels, and the difference between laboratory conditions and consumer use.

However, this was more commonly the view of some consumers, professional groups, authorities and parts of academia, rather than industry overall. These groups tended to focus on consumer comprehension, health literacy and the need to avoid a misleading impression of precision. Professional respondents, in particular, often argued that categorical descriptors may better reflect SPF as a range rather than an exact value and could reduce misunderstanding about the significance of very high SPF claims. Academic respondents similarly saw category-based systems as potentially more accessible for people with lower scientific or numerical literacy, although many still preferred a hybrid model that retained some connection to SPF.

That said, option 3 was much more contentious among industry and many consumers. Domestic and international industry respondents were generally reluctant to replace the SPF numerical system, arguing that this would create confusion, diverge from international practice, and impose substantial implementation costs. Many consumers also worried that replacing SPF numbers altogether could reduce clarity and confidence unless any new system was carefully tested, well explained, and aligned with international approaches. So even where respondents saw merit in reform, many preferred a hybrid or staged approach rather than complete replacement.

Overall

Overall, option 1 tended to be supported where respondents prioritised familiarity, international consistency and avoiding unnecessary disruption, especially among industry, consumers and many not-stated respondents. Option 2 was often seen as the most pragmatic middle path, particularly by consumers, academia, authorities and some international industry respondents, because it could improve understanding while retaining the trusted SPF system. Option 3 attracted support from respondents more focused on real-world performance, testing variability and health literacy, especially among professional groups, some consumers, authorities and academics, although support was often conditional on careful design, public education and some continuing link to SPF.

A strong cross-cutting theme across all 3 options was that respondents thought UVA labelling is a major gap. Even where there was disagreement about SPF labelling reform, many respondents said clearer, standardised UVA information would be important regardless of which option is adopted.

TGA response to matter 3

The TGA notes that consultation feedback reflected materially different views across respondent groups on whether and how SPF labelling should be reformed. Support for retaining the current SPF numerical system, or making only limited additive changes, was strongest among domestic and international industry respondents, and many consumers. These groups generally emphasised familiarity, international alignment, and the risk that changing a long-established labelling system could create confusion, increase costs, and undermine confidence without addressing the underlying issue of testing reliability. In contrast, support for more substantive reform was more common among professional respondents, some consumers, authorities and parts of academia, who were more likely to focus on health literacy, real-world performance, testing variability and the potential for precise SPF numbers to create a misleading impression of certainty.

The TGA acknowledges that the SPF system is long-standing and internationally recognised, and that this familiarity remains important to consumers and industry. However, the consultation paper identified several reasons why reform should be considered. SPF is a relative measure of UVB protection derived under controlled laboratory conditions, but actual sunscreen performance depends on a range of real-world factors,

including solar intensity, skin type, amount applied, reapplication frequency and user activity such as sweating or swimming. While many industry and consumer respondents argued that the current numerical system remains useful and well understood, professional and academic respondents more often emphasised that these real-world variables limit the practical meaning of precise SPF numbers and support reconsideration of how sunscreen performance is communicated.

The consultation also highlighted that consumer understanding of SPF is limited, although views differed on whether this should be addressed through labelling reform, education, or both. Mainly consumer and some other respondents who supported retaining the status quo often argued that numerical SPF remains the clearest and most familiar format, and that broader categories or simplified graphics could reduce clarity and obscure meaningful differences between products.

In contrast, professional respondents, some consumers, authorities and academics were more likely to argue that SPF figures are often interpreted too literally, despite the fact that the scale is not linear and that the practical difference in UVB protection between higher SPF values is relatively small. For example, when applied correctly, SPF 30 filters approximately 97% of UVB rays, while SPF 50 filters approximately 98%. These respondents generally considered that precise numerical claims may overstate real-world differences in protection and may not support good consumer understanding, particularly at the higher end of the scale.

The TGA also notes the concerns raised in the consultation paper about the variability of current *in vivo* SPF testing methods. This issue was particularly important to respondents who supported reform, including professional and academic stakeholders and some authorities, who considered that precise numerical labelling can imply a degree of scientific certainty that is not always supported by reproducible test results. At the same time, many industry and consumer respondents argued that this variability points to the need for better testing methods and regulatory oversight, rather than major changes to the labelling framework itself. The TGA considers both perspectives relevant. A lack of reproducibility in testing can make it difficult for sponsors to confidently determine a precise SPF claim and can create ambiguity in regulatory compliance, particularly at the upper end of the SPF scale. This raises a legitimate question as to whether the current labelling framework communicates sunscreen performance in the most appropriate way.

Taken together, the consultation suggests that there is a credible case for reforming how sunscreen performance is communicated to consumers, but also that stakeholder confidence in any reform will depend on careful design and implementation. Respondents favouring reform generally did so because they considered that the current framework places too much emphasis on numerical precision and not enough on real-world use, testing variability and consumer comprehension. Respondents favouring the status quo or limited change generally placed greater weight on familiarity, international consistency and avoiding unintended confusion. The TGA considers that any future reform would need to balance these considerations and be supported by consumer testing, public education and clear transition arrangements.

The TGA also notes the strong and consistent feedback across respondent groups that UVA labelling is a significant gap in the current framework. Even among respondents who supported retaining the current SPF system, many considered that clearer, standardised UVA information is needed to better communicate broader sun protection. This was particularly emphasised by professional and academic respondents but was also raised across consumers and industry. The TGA notes that this matter may warrant further consideration regardless of the final approach to SPF labelling reform.

TGA Recommendation for Reform

Consultation feedback showed mixed views on SPF labelling reform.

While we consider SPF labelling an important element of the overall reform package, we will undertake further review and consultation at a later stage before progressing any proposed labelling changes.

Consultation matter 4: Cosmetic sunscreens able to make high SPF claims

The current provisions in the Excluded Goods Determination 2018 exclude tinted bases, foundations and lip products with SPF claims up to SPF 50+ from being therapeutic goods.

Options proposed to address Issue 4

- Option 1: Status quo – maintain current exclusion provisions for cosmetic sunscreens.
- Option 2: Amend the Excluded Goods Determination to require that excluded sunscreens include 'cosmetic sunscreen' on their primary label.
- Option 3: Amend the Excluded Goods Determination to provide a consistent limit of the SPF rating that can be claimed for all secondary (cosmetic) sunscreens.

Overall summary of stakeholder responses to matter 4

Option 1: Status quo.

Support for option 1 was generally based on the view that the current framework is broadly working and that there is not enough evidence that secondary or cosmetic sunscreen arrangements are failing. A common reason given was that products such as lip balms, foundations, tints and other hybrid cosmetic-SPF products support everyday sun protection habits and should remain available without unnecessary restriction. Respondents supporting this option often argued that limiting SPF claims or introducing new terminology could reduce consumer choice, increase costs, create supply and trade complications, and potentially remove products from the market.

However, this was primarily the view of industry (domestic and international), and to some extent some consumers. These groups tended to focus on proportional regulation, access to products, international alignment and the practical consequences of reform for manufacturers and supply chains. Consumers who supported option 1 also questioned whether there was sufficient evidence that people are actually confusing cosmetic SPF products with primary sunscreens, and said that if there is a problem, it may be better addressed through education rather than regulatory change.

That said, professional respondents gave option 1 a different emphasis. They were less focussed on preserving the existing framework for market reasons and more on the fact that cosmetic products are used differently in practice and are not usually applied in sufficient quantity or frequency to deliver labelled SPF in real-world use. Some also noted that, despite this, clearer SPF and UVA information on secondary sunscreens could still be important for people with photosensitive or pigmentary conditions.

Option 2: Amend the Excluded Goods Determination to require that excluded sunscreens include 'cosmetic sunscreen' on their primary label.

Support for option 2 was generally framed as a middle-ground approach. Respondents saw it as a way to improve transparency and help consumers distinguish cosmetic or secondary sunscreen products from primary sunscreens, without fully removing such products from the market or imposing the same regulatory burden as therapeutic sunscreens. The main rationale was that clearer labelling and warning statements could help communicate that these products are not intended to replace a primary sunscreen and should be used alongside one.

However, this view was most strongly associated with consumers, academia and authorities, rather than industry as a whole. These groups tended to see clearer labelling as a practical and lower-burden reform that could improve consumer understanding while preserving access to products people already use. Academic respondents, in particular, tended to frame option 2 as a balanced response that avoids discouraging everyday SPF use. Authorities also tended to support clearer "cosmetic sunscreen" labelling, often alongside some limits or warning requirements, as a way to balance better consumer information with continued market access.

By contrast, many industry respondents were sceptical of option 2. Domestic and international industry respondents often argued that the term “cosmetic sunscreen” would not be well understood by consumers and could instead create confusion or imply that such products are inferior, despite being tested to the same SPF standards. They also pointed to packaging costs, implementation burden and limited evidence that the new terminology would improve public health outcomes. So, while option 2 attracted support across several groups, it was not seen uniformly as an effective solution.

Option 3: Amend the Excluded Goods Determination to provide a consistent limit of the SPF rating that can be claimed for all secondary (cosmetic) sunscreens.

Support for option 3 was generally based on concerns about consumer misunderstanding, public health risk and regulatory consistency. Respondents favouring this option argued that high SPF claims on cosmetic products can be misleading because consumers may interpret them as equivalent to therapeutic sunscreens, even though the products are not regulated in the same way and are not usually used under the same conditions as primary sunscreens. A recurring theme was that cosmetics are often applied in smaller quantities, not reapplied, and may lack the water resistance or usage patterns needed to deliver the labelled protection in practice. On this basis, some respondents supported capping SPF claims, limiting cosmetic products to lower SPF levels, or requiring any product making higher SPF claims to come under fuller regulatory oversight.

However, this was more commonly the view of consumers, professional groups, some academics, “other” respondents, and many not-stated respondents. These groups tended to emphasise public health, fairness between regulatory categories, and the need to avoid a false sense of protection. Consumers supporting option 3 were particularly concerned about a regulatory gap, arguing that high SPF claims should only be permitted where products meet equivalent TGA evidentiary and regulatory requirements. Professional and academic respondents also often supported a cap on the basis that it would better reflect real-world use and simplify messaging, particularly where cosmetic products are not reapplied.

That said, industry views on option 3 were much more divided and often opposed. Domestic and international industry respondents were more likely to argue that an SPF cap would reduce consumer choice, increase costs, create reformulation and manufacturing challenges, and discourage innovation in high-protection products. Some also argued that there was no clear evidence the reform would improve outcomes and that it could lead consumers to seek imported products outside the Australian framework. Even where some industry respondents saw merit in improving consistency, they generally urged caution about the practical effects.

Overall

Overall, option 1 tended to be supported where respondents prioritised product access, international alignment and avoiding unnecessary burden, especially among industry and some consumers. Option 2 was more often seen as a moderate, transitional response, particularly by consumers, academia and authorities, who wanted better differentiation without major market disruption. Option 3 attracted strongest support from respondents focused on public health, consumer behaviour and regulatory consistency, especially consumer advocates, professionals and some academics, although it was more contentious among industry, who were more concerned about feasibility, cost and reduced product availability.

TGA response to matter 4

The TGA notes that consultation feedback reflected materially different perspectives across respondent groups on whether and how the current framework for cosmetic sunscreens able to make high SPF claims should be reformed. Support for maintaining the status quo was strongest among both domestic and international industry respondents, and to a lesser extent some consumers, who generally emphasised proportional regulation, continued consumer access, international alignment, and the practical risks that reform could impose on product availability, supply chains and manufacturing. These respondents often argued that there is limited evidence that the existing arrangements are failing, and that if consumer misunderstanding exists, it may be more appropriately addressed through education rather than through regulatory change.

In contrast, stronger support for reform—particularly option 3—came more often from consumers, professional groups, some academic respondents, and “other” respondents. These groups were more likely to focus on consumer behaviour, public health risk and regulatory consistency. A recurring concern among these respondents was that high SPF claims on excluded cosmetic products may lead consumers to assume that such products provide equivalent protection to therapeutic sunscreens, despite not being regulated in the same way and not generally being used under the same conditions. Professional and academic respondents in particular often emphasised that cosmetic products are typically applied in smaller quantities, are not usually reapplied every 2 hours, and may therefore not deliver the labelled protection in real-world use.

The TGA also notes that support for option 2 was more commonly associated with consumers, academia and authorities, who tended to see clearer labelling and warning statements as a more moderate way to improve transparency and help distinguish cosmetic sunscreen products from primary sunscreens without creating the same degree of disruption as an SPF cap. However, many industry respondents were sceptical of this approach, arguing that the term “cosmetic sunscreen” may not be well understood by consumers and could instead create confusion or imply that these products are inferior, despite being tested to the same SPF standards.

The consultation paper nevertheless identified substantial issues that go beyond stakeholder preference. Under the current framework, products such as tinted bases, foundations and lip products may be excluded from therapeutic regulation while still making high SPF claims, provided they meet specified criteria. At the same time, Australian consumers are familiar with the SPF rating scale and may reasonably interpret high SPF claims in the same way regardless of whether the product is regulated as a cosmetic or as a therapeutic sunscreen. This creates a risk that excluded products may be used by consumers as if they were primary sunscreens, despite not being subject to equivalent regulatory oversight. The TGA considers that this raises an issue of regulatory consistency, particularly where high SPF claims may imply a level of evidentiary assurance, manufacturing oversight and compliance scrutiny that does not apply in the same way to excluded cosmetic products.

The TGA also gives weight to the concerns raised by professional, academic and consumer respondents that cosmetic products are used differently from primary sunscreens in practice. Products such as make-up and lip balms are generally applied in lower quantities, are not typically reapplied at the frequency recommended for primary sunscreens and may not have the same water resistance or usage profile. This means that, even where a labelled SPF claim is technically substantiated, the protection achieved in real-world use may be materially lower than consumers assume. In this respect, the TGA notes that the consultation paper’s concern about a false sense of protection was strongly reflected in submissions supporting reform, particularly among respondents focused on public health and health literacy.

At the same time, the TGA acknowledges the concerns raised by industry and some consumers that reform could reduce consumer choice, increase costs, create reformulation and manufacturing challenges, and affect supply and trade. The TGA also notes the argument that some cosmetic SPF products may support everyday protective habits and that any reform should avoid unintended consequences, including discouraging routine use of products that provide at least some supplementary protection.

On balance, the TGA considers that the consultation identified a credible case for reform, while also showing that implementation risks must be carefully managed. The evidence and submissions supporting reform were strongest where respondents focused on the risk that high SPF claims on excluded cosmetic products may overstate real-world protection and create inconsistency between consumer expectations and regulatory oversight. At the same time, concerns raised by industry and some consumers indicate that any reform should be proportionate, clearly communicated, and supported by transition arrangements that minimise unnecessary disruption.

TGA Proposed Reform

Option 3: Amend the Excluded Goods Determination to provide a consistent limit of the SPF rating that can be claimed for all secondary (cosmetic) sunscreens.

The TGA considers that option 3 is the preferred basis for reform, supported by appropriate transition arrangements and implementation safeguards.

Consultation matter 5: Opportunities to enhance sunscreen manufacturing guidance

Our recent investigations of sunscreen manufacturers have not revealed any specific manufacturing issues that explain why a number of sunscreens were identified with low SPF results. However, our inspection data has identified matters that could be improved by the TGA providing greater clarity on existing GMP expectations

Options proposed to address Issue 5

- Option 1: Status quo – maintain current GMP guidance for sunscreen manufacturers.
- Option 2: Review sunscreen GMP guidance to incorporate contemporary information and address any additional risks.

Overall summary of stakeholder responses to matter 5

Support for Option 2 was strongest among consumers and professional respondents, who considered that updated manufacturing guidance would improve confidence in sunscreen quality, performance, stability and consistency. Academic and authority respondents also generally supported reviewing the guidance to better reflect current knowledge and support clearer, risk-based regulatory expectations.

Domestic industry respondents generally supported updating guidance, but views were more mixed. While many supported clearer expectations for sponsor–manufacturer responsibilities, batch release, outsourced manufacturing and consistent GMP interpretation, some considered the existing guidance adequate and suggested recent issues would be better addressed through compliance and enforcement. International industry respondents emphasised maintaining alignment with established GMP frameworks and avoiding additional complexity or duplication. Other and not-stated respondents expressed mixed views, supporting improved clarity and confidence while also noting the need to maintain flexibility and avoid unnecessary regulatory burden.

TGA response to matter 5

The TGA acknowledges that consultation feedback indicated broad support for reviewing and updating sunscreen manufacturing guidance to ensure it remains contemporary, clear and fit for purpose. Most respondents considered that while existing GMP guidance is broadly appropriate, there are opportunities to improve clarity, consistency and accountability across the manufacturing framework.

The TGA notes that support for updating guidance was generally linked to the view that recent issues have highlighted areas where expectations could be more clearly articulated, particularly in relation to sponsor–manufacturer responsibilities, knowledge management, control of critical quality attributes, and product release processes. Respondents also emphasised the importance of ensuring that any updated guidance supports consistent interpretation of GMP requirements and promotes reliable manufacturing outcomes.

At the same time, the TGA acknowledges that some respondents considered that existing guidance is sufficient and that recent issues are more appropriately addressed through strengthened compliance, oversight and enforcement rather than regulatory change. These submissions highlighted the importance of maintaining a risk-based approach and avoiding unnecessary regulatory burden.

The TGA considers both perspectives relevant. While current GMP requirements provide a sound framework for manufacturing listed medicines, including sunscreens, the consultation indicates that additional clarity in

guidance may assist sponsors and manufacturers to better understand and meet regulatory expectations in areas that are particularly relevant to sunscreen products. This includes aspects such as process validation approaches, control of formulation variability, stability considerations and the management of outsourced manufacturing arrangements.

The TGA also notes the consistent feedback that any changes should be proportionate, practical and aligned with existing international GMP frameworks. The TGA agrees that updated guidance should not introduce unnecessary prescriptive requirements but should instead support a risk-based approach that targets known or emerging areas of manufacturing risk.

Taken together, the consultation supports a targeted review and update of sunscreen manufacturing guidance to improve clarity and consistency, while maintaining the existing risk proportionate GMP framework. The TGA considers that updated guidance, supported by appropriate stakeholder engagement and implementation arrangements, would assist in strengthening compliance and confidence in the quality of sunscreen products supplied to Australian consumers.

TGA Proposed Reform

Option 2 – Review sunscreen GMP guidance to incorporate contemporary information and address additional risks.

The TGA considers that option 2 provides the most appropriate and proportionate approach to addressing the issues identified through consultation.

Under this approach, the TGA would undertake a targeted review of existing sunscreen manufacturing guidance to:

- clarify expectations for sponsor–manufacturer responsibilities and oversight arrangements
- provide additional guidance on the identification and control of critical quality attributes and process parameters relevant to sunscreen formulations
- strengthen guidance on process validation, stability and batch to batch consistency
- support improved knowledge management and traceability across the manufacturing lifecycle.

Any updates would be designed to:

- maintain alignment with existing GMP requirements and international frameworks
- be proportionate to the lower risk profile of listed medicines
- avoid unnecessary increases in regulatory burden for sponsors and manufacturers.

The TGA will engage with stakeholders as part of the review process and will consider appropriate implementation and transition arrangements to support practical adoption.

This approach is expected to improve consistency in GMP interpretation, strengthen manufacturing outcomes, and support continued confidence in the quality and performance of sunscreen products in Australia.

Version history

Version	Description of change	Author	Effective date
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