Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

# Proposed adoption of an Australian Sunscreen Exposure Model

## Impact Analysis
## Therapeutic Goods Administration
## Department of Health & Aged Care

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# Contents

# Executive summary

The primary objective of the regulation of sunscreens in Australia is to ensure their quality, safety and efficacy to protect consumers from the sun's harmful ultraviolet radiation (UVR) and reduce the incidence and tragic outcomes of skin cancer. The Therapeutic Goods Administration (TGA) regulates sunscreens in Australia [under the *Therapeutic Goods Act 1989* (the Act)] that are classified as therapeutic goods to make sure they are safe, efficacious and high quality.

Exposure to UVR is a significant risk factor and is known to cause skin cancer in humans (IARC 1992). UVR is linked to approximately 95% of melanoma cases in the country (Cancer Australia 2019). Preventative UVR exposure measures, such as using sunscreens, are an effective strategy against developing skin cancer (Green et al. 2011; Olsen et al. 2015). Despite being the last recommended line of defence after other protective measures, such as seeking shade and wearing UV protective clothing, sunscreens are one of the most common methods of sun protection (Stanton et al. 2004) and suggested to be a cost-effective method for preventing skin cancer (Gordon et al. 2009; Gordon et al. 2020).

While Australians widely use sunscreen, individual application varies based on factors such as daily habits, occupational exposure and recreational activities. Australians are increasingly aware of sun safety and are using sun protection measures (Cancer Australia 2019) which may be due to increased promotion and public awareness of their importance and benefits. As such, the way sunscreens were used in the past is likely to differ to how they are used today.

Before a therapeutic sunscreen product can be marketed and supplied to consumers in Australia, the TGA must have approved the ingredients used in the product and established their maximum safe concentration. Sponsors (product owners or manufacturers) are legally bound to adhere to these TGA-mandated concentration limits. Risk assessments for sunscreen ingredients typically focus on long-term exposure to the ingredient, but they also address acute safety concerns like potential skin irritation. The risks associated with use of ingredients compare the associated (health) hazards to the expected systemic (or internal) exposure of the ingredient absorbed through the skin into the body. This assessment helps ascertain the maximum safe concentration of an ingredient.

Determining the systemic exposure, and consequently, the safe concentration of the sunscreen ingredient, is based on how much sunscreen is applied to the skin on a daily basis (i.e. the external exposure amount). There is little contemporary data on how much sunscreen Australians apply to their skin and the amount used is variable and difficult to estimate as sunscreen usage varies greatly.

The Australian Cancer Council's recommends applying 140 mL sunscreen application for a full-day full body sun exposure. However, actual Australian use may not always align with recommendations for how sunscreens are to be used effectively and different methods for calculating the external exposure may not fully capture Australian usage patterns.

Sunscreen exposure considerations differ internationally, with the European Scientific Committee on Consumer Safety's (SCCS) estimating exposure model being one of the main approaches that is also utilised by applicants in Australia. However, this model is based on data from research conducted in countries outside Australia. It is unclear if this is relevant for the Australian context, given we have the highest rates of skin cancer in the world, a focus on public health messaging on the importance of using sunscreens, a thinner ozone layer and an outdoor lifestyle. Further, because of their public health importance, sunscreens that are primarily for prevention of skin cancer are regulated as therapeutic goods in Australia and based on their Sun Protection Factor (SPF), are able to make skin cancer prevention claims, while sunscreens are regulated as cosmetics in Europe and are not permitted to make the same high-level claims.

In addition, depending on the available data, the SCCS exposure calculation method can yield considerably different risk assessments for the same ingredient. This discrepancy could result in the same ingredient being approved under one set of data but rejected if presented in a different way. Such inconsistencies raise concerns about the appropriate calculation method for regulatory approvals and the potential for regulatory uncertainty, requiring expert judgement for which calculation

method will be most suitable. The type of information that is presented by the applicant could also contribute to inconsistent assessments.

To date, TGA assessment for sunscreen ingredients is on a case-by-case basis through a variety of risk-based methodologies that may use different estimates of daily sunscreen exposure. This results in the following problems:

- The absence of an agreed estimated daily sunscreen exposure value means there is no standardised method for evaluating sunscreen ingredients, potentially leading to discrepancies in risk assessments where some may be overly conservative, while others may not be conservative enough. This means the same ingredient could be approved or refused based on the same data.
- Regulatory inconsistencies lead to uncertainty for industry. This is problematic given the lengthy research and development process required to bring new ingredients to market, with tests that may need to be conducted at the proposed concentration for final products. Uncertainty about the concentration that may be approved by the TGA, based on the assessment methodology, could stifle innovation and development of new ingredients.
- Without an Australian accepted approach, evaluations are more prone to being challenged, leading to increased time and resources expended by all stakeholders in debating application decisions. This not only delays the introduction of new sunscreen ingredients but also burdens the regulatory process with unnecessary contention.
- Applicants may be required to provide scientifically robust arguments to support their chosen approach, which may not be supported by the TGA evaluator if not well-founded. Given the complexity of assessing sunscreen exposure, this could pose significant challenges and add unnecessary time and regulatory costs for new ingredient applicants.
- Some estimated daily sunscreen exposure values proposed by applicants may not adequately reflect the unique Australian context, such as the higher levels of UV exposure and adherence to current evidence-based guidelines for effective sun protection. The methods employed may not account for Australian practices today for the most frequent sunscreen users.

Currently, there are increasing scientific concerns, both domestically and internationally, over long-term use of some current sunscreen ingredients which have the potential to decrease consumer confidence in the use of sunscreens and, has created uncertainty for the sunscreen industry about what action the TGA, and overseas regulators, may take in relation to these ingredients.

In August 2023, the TGA initiated a public consultation to determine the safe levels of benzophenone (a degradation impurity) in sunscreens containing octocrylene. The assessment utilised the Cancer Council's full-day sunscreen application recommendation, equating to 140 mL for a full body, to calculate the maximum worst-case sunscreen exposure. While one respondent supported this approach, the majority of industry feedback considered this estimate was overly conservative, not reflective of Australian consumer usage and did not consider additional recommended sun protective measures.

Industry stakeholders provided varied perspectives on the appropriate method for exposure assessment. The diversity of opinions highlighted the need for an exposure model that aligns with Australian guidelines and practices, which was supported by stakeholders. As such, the TGA advised in December 2023 that it would develop a sunscreen exposure model for the Australian context with future consultation to be undertaken. The proposed changes regarding setting an acceptable regulatory limit for benzophenone were deferred pending the development of this model.

The TGA has now developed a proposed Australian Sunscreen Exposure Model (ASEM) which was subject of an industry consultation between July and August 2024. The proposed exposure model aligns with current evidence-based sunscreen use guidelines and concerted efforts to encourage correct application of sunscreens, such as those described in the Australian Government's National Skin Cancer Prevention campaign, the Cancer Council Australia's well-known SunSmart program, the 2023 position statement by Australian Skin and Skin Cancer Research Centre, the 2019 Australian and New Zealand evidence-based consensus statement on when to apply sunscreen, and many

other organisations such as the Melanoma Institute Australia, Australasian College of Dermatologists, and Safe Work Australia.

This Impact Analysis proposes the following three options for a method to calculate safe levels of new ingredients proposed for use in Australian sunscreens:

**Option 1**: **Australian Sunscreen Exposure Model (ASEM):**

The ASEM calculates the estimated average daily sunscreen exposure based on the varied needs of Australians. The ASEM integrates expected sunscreen application practices in line with current evidence-based Australian recommendations, rather than relying on international models.

The ASEM confirms the safety of sunscreen ingredients by considering the highest plausible, estimated average daily sunscreen exposure among regular sunscreen users. The model considers these situations by employing six theoretical evidence-based Australian exposure scenarios for the most frequent users and, assessing the risk of the ingredient based on the highest exposure. This ensures that if an ingredient is deemed safe for the highest exposure, it will also be safe for all Australians.

**Option 2**: **Scientific Committee on Consumer Safety (SCCS) sunscreen exposure model:**

This SCCS sunscreen exposure model is a well-established approach that describes default estimated daily sunscreen exposure (e.g. 18 g/day) as detailed in the SCCS's guidance for testing cosmetic ingredients (12$^{th}$ revision). This model is recognised by some international regions such as Europe, where sunscreens are regulated as cosmetics and the model has also been employed in previous TGA assessments and submitted by sunscreen ingredient applicants.

**Option 3**: **Status Quo:**

This option does not adopt a specific estimated daily sunscreen exposure model. Instead, evaluation of sunscreen ingredients will be on a case-by-case basis, with the applicant able to use various approaches providing they can provide an acceptable justification for their approach.

**Preferred option**

The TGA prefers Option 1 as it will provide regulatory certainty for industry and increase Australian consumer confidence in the safety of sunscreens. The ASEM will provide a consistent and transparent process for assessing the safety of sunscreen ingredients that aligns with Australian conditions and consumer practices. This will provide regulatory certainty and a fair framework for industry applications, while reinforcing consumer expectations that sunscreens approved for use in Australia are safe to be used by everyone, no matter age or outdoor activity.

The majority of respondents to the recent consultation also support Option 1.

Adoption of the ASEM will be a decision of a delegate of the Secretary of the Department of Health and Aged Care.

# Background

The Therapeutic Goods Administration (TGA) regulates therapeutic sunscreens that protect Australians against the sun's harmful ultraviolet radiation (UVR). UVR is a major health concern linked to approximately 95% of melanoma cases in the country (Cancer Australia 2019).

Exposure to UVR is a significant risk factor and is known to cause skin cancer in humans (IARC 1992). Preventative UVR exposure measures, such as using sunscreens, are an effective strategy against developing skin cancer (Green et al. 2011; Olsen et al. 2015). Despite being the last recommended line of defence after other protective measures, such as seeking shade and wearing UV protective clothing, sunscreens are one of the most common methods of sun protection (Stanton et al. 2004) and suggested to be a cost-effective method for preventing skin cancer (Gordon et al. 2009; Gordon et al. 2020).

While Australians widely use sunscreen, individual application varies based on factors such as daily habits, occupational exposure and recreational activities. Australians are increasingly aware of sun safety and are using sun protection measures (Cancer Australia 2019) which may be due to increased promotion and public awareness of their importance and benefits. As such, the way sunscreens were used in the past is likely to differ to how they are used today.

## Skin cancer rates in Australia

Populations that live in areas with intense ambient UVR and who work and spend leisure time outdoors in the sun are at increased risk of developing skin cancer. Skin cancer can be broadly classified into two categories:

- non-melanoma keratinocyte cancers, including basal cell carcinomas (BCC) and squamous cell carcinomas (SCC), which are the most prevalent types
- malignant melanomas, which have a high mortality rate.

In Australia, skin cancer is a major health issue, and we have one of the highest rates of skin cancer in the world. Age-standardised incidence rates for cutaneous melanoma in Australia are more than double to triple the incidence reported for Canada, the United States and the United Kingdom. At least two in three Australians will be diagnosed with skin cancer before the age of 70 (Morton et al. 2023).

Skin cancer accounts for the largest number of cancers diagnosed in the Australasian region each year, resulting in significant morbidity and mortality. The Australasian College of Dermatologists states that the age-standardised incidence rate for melanoma in 1982 was 26.7 cases per 100,000 persons. The Australian Institute of Health and Welfare[1] state that skin melanoma incidence rates have increased as follows:

- 54 cases per 100,000 people in 2000
- 69 cases per 100,000 people in 2023

In 2023, 18,257 people were estimated to be diagnosed with melanoma which was the third most common cancer diagnosed in Australia, comprising 11% of all diagnosed cancers. It is estimated that:

- 35% of skin melanoma cases are diagnosed on the trunk of the body
- 26% on the upper limbs, including shoulder
- 18% on the lower limbs, including hip
- 7.6% on the scalp and neck

[1] https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/contents/overview-of-cancer-in-australia-2023

Keratinocyte carcinomas are the most common cancer diagnosed in Australia, accounting for 959,243 paid Medicare services in 2014 (Australian institute of Health and Welfare, 2023)[2].

The incidence rate for melanoma increases with age, peaking between 85 and 89 years of age. Melanoma rates also differ by state and/or territory, with people living in Queensland at highest risk of developing melanoma, followed by Tasmania, New South Wales, Western Australia, Australian Capital Territory, Northern Territory, Victoria and South Australia (Australian Institute of Health and Welfare, 2023)[2].

While melanoma incidence rates for people aged 50 and over continue to rise, incidence rates have been decreasing for people aged under 40 since the late 1990s. The Australian Cancer Council 'Slip Slop Slap' campaign was a large skin cancer awareness campaign that commenced in the early 1980s. Skin cancer awareness and prevention advice continues today. In 2023, the population aged under 40 were born after the 'Slip Slop Slap' campaign commenced and have spent their lives in an environment where skin cancer awareness has been greater, while people aged 50 and over have spent more of their lives in times when there was less skin cancer awareness (Australian Institute of Health and Welfare, 2023)[2].

In relation to mortality rates, data from the Australian Bureau of Statistics[3] is that 1897 people died in 2010 and 2093 people died in 2019 from malignant neoplasms of the skin (Table 1).

**Table 1: Underlying cause of death, Australia, 2010–2019**

| | 2010 | | | 2019 | | |
|---|---|---|---|---|---|---|
| | **Males** | **Females** | **Persons** | **Males** | **Females** | **Persons** |
| **Total population** | | | 22,166,335 | | | 25,510,998 |
| **Total deaths from all causes** | 73,484 | 69,989 | 143,473 | 88,346 | 80,955 | 169,301 |
| **Deaths from melanoma and other malignant neoplasms of skin** | 1297 | 600 | 1897 | 1406 | 687 | 2093 |

Skin melanoma mortality age-adjusted rates peaked at 8 deaths per 100,000 people in 2013. In 2023, there were estimated to be 1,314 deaths from melanoma (with the estimated age-adjusted mortality rate of 5 deaths per 100,000 people) (The Australian Institute of Health and Welfare, 2023)[2].

In 1995–1999, 5-year skin melanoma survival rates were a little over 90%. In 2015-2019, the five-year relative survival rate for melanoma was almost 94%. Survival rates vary considerably by stage at diagnosis. For people diagnosed at Stage I (thin tumours and localised disease) the 5-year relative survival rate for melanoma is nearly 100%, but only 26% when diagnosed at Stage IV (metastatic disease). Improvements in survival could be associated with earlier detection and diagnosis. (Australian institute of health and Welfare, 2023)[2].

Skin cancer, both melanoma and keratinocyte carcinomas are responsible for the highest cancer- related health system expenditure at more than $1.6 billion, placing significant burden on Australia's healthcare system (Australian Institute of Health and Welfare, 2021)[4]. Skin cancer is the most expensive cancer to treat in Australia – more than breast, prostate or lung cancer. Ongoing national investment in prevention, early detection and treatment is needed (Australian College of Dermatologists, 2023)[5].

[2] www.aihw.gov.au/reports/cancer/cancer-data-in-australia/contents/overview
[3] https://www.abs.gov.au/statistics/people/population/deaths-australia/2022
[4] www.aihw.gov.au/reports/health-welfare-expenditure/spending-on-disease-in-australia/data
[5] www.dermcoll.edu.au/wp-content/uploads/2023/09/ACD-Statement-Impact-of-skin-cancer-in-Australia-August-2023.pdf

# Ultraviolet radiation

Solar emissions include visible light, heat and UVR. The sun is the strongest source of UVR in our environment. There are also artificial sources of UVR including: welding; tanning beds; nail curing devices; signature recognition; bug zappers; fluorescence lights; curing of printing inks; medical devices; sterilisation and purification equipment[6].

The UVR spectrum is divided into 3 regions called UVA, UVB and UVC according to wavelength:

- UVC (100-280 nm) - is the shortest wavelength and the most damaging type of UVR, however, as sunlight passes through the atmosphere, water vapour, oxygen and carbon dioxide, all UVC is absorbed[7].
- UVB (280–315 nm)[7] - most UVB is absorbed by the atmosphere, UVB comprises 5% of the solar UVR reaching the earth's surface.
- UVA 315–400 nm[7] - UVA is not filtered significantly by the atmosphere The majority of solar UVR reaching the earth's surface (approximately 95%) is UVA.

Exposure to UVR via sun exposure is estimated to cause around 95% of melanoma cases in Australia (Cancer Australia)[8]. Both UVA and UVB can cause deoxyribonucleic acid (DNA) damage. UVA has less energy than UVB and is responsible for skin tanning and skin aging. UVB has a shorter wavelength and higher energy, and it only reaches the epidermis layer of skin. UVB is the primary cause of erythema, a radiation-induced inflammatory response appearing as the reddening of the skin, commonly known as sunburn (Zou et al. 2022).

UVR comes from both direct sunlight and indirect sources. Substantial amounts of the sun's UVR are scattered from the open sky and reflected from the environment (e.g. snow, sand, water, clouds and the sky itself). This means that a person can be sunburned in shade and that the risk of sunburn is greatly increased near sources of reflected radiation, such as snow and water. UVR from the sun reaching the skin is a continuous process with the skin accumulating damage as long as it is exposed to the sun. This may lead eventually to premature ageing of the skin, skin cancer and other adverse effects[9].

## Protection from ultraviolet radiation

It is important to take preventive measures to limit UVR exposure, as exposure to UVR is the main preventable cause of skin cancer. Exposure to UVR can be moderated by protective behaviours, such as seeking shade, wearing a hat, wearing protective clothing and sunscreen.

There is a long history of health campaigns aimed at reducing skin cancer in Australia. The Cancer Council Australia launched the “Slip, Slop, Slap” campaign in 1981, which was updated in 2007 to “Slip, Slop, Slap, Seek, Slide” which means slipping on sun protective clothing; slopping on sunscreen; slapping on a broad-brimmed hat; seeking shade when and where possible; and sliding on sunglasses. Cancer Council Australia states that the campaign is widely credited as playing a key role in the dramatic shift in sun protection attitudes and behaviour in Australia.

Public health campaigns encourage the use of sunscreens, as one of the measures to prevent the harmful effects of UVR. In general, sunscreens contain active ingredients that can absorb, reflect, or scatter UV rays, to protect the skin against UVR induced skin damage. The active ingredients in sunscreens can be either inorganic materials such as titanium dioxide (TiO2) and zinc oxide (ZnO), or organic compounds such as oxybenzone, octocrylene, butyl methoxy dibenzoylmethane, etc. (Zou et al. 2022).

[6] https://www.arpansa.gov.au/our-services/testing-and-calibration/ultraviolet-radiation-testing/assessment-of-ultraviolet-hazards

[7] World Health Organisation https://www.who.int/news-room/questions-and-answers/item/radiation-ultraviolet-(uv)

[8] https://ncci.canceraustralia.gov.au/prevention/sun-exposure/sunburn-and-sun-protection

[9] AS/NZS 2604:2021, *Sunscreen products - Evaluation and classification* for sunscreens

# Sunscreen regulation in Australia

In Australia, sunscreens are regulated as either cosmetics or therapeutic goods depending on several factors, such as their ingredients, health claims and claimed SPF. The objective of regulation of sunscreens is to ensure their quality, safety, and efficacy to protect consumers from the sun's harmful UVR and reduce the incidence and tragic outcomes of skin cancer.

## Primary and secondary sunscreens

Sunscreens fall into 2 categories: "primary" sunscreens and "secondary" sunscreens. The Australian therapeutic goods legislation relies on the definition of primary and secondary sunscreens provided in the Australian/New Zealand Standard for sunscreens (AS/NZS 2604:2021, *Sunscreen products - Evaluation and classification* for sunscreens) (the **2021 Sunscreen Standard**) as reproduced below:

1. **Primary sunscreen product:** Product that is represented as being primarily to protect the skin from UV radiation.

2. **Secondary sunscreen product:** Product that is represented as having a primary function other than sun protection whilst providing some protection of the skin from UV radiation lips

## Therapeutic sunscreens

Under the *Therapeutic Goods Act 1989* (the Act) and supporting legislation, sunscreen products that are regulated as therapeutic goods (also known as "**therapeutic sunscreens**") by the TGA include:

- Primary sunscreens

- Some secondary sunscreens: Products with a primary purpose other than sun protection, that also contain sun screening agents but are not excluded (see below) from therapeutic goods legislation e.g. sunbathing and moisturising skin care products with an SPF over 15.

Many secondary sunscreen products are not considered to be therapeutic goods and are "excluded" from therapeutic goods legislation. These product types are outlined under the *Therapeutic Goods (Excluded Goods) Determination 2018* (Excluded Goods Determination). These include moisturisers with an SPF less than 15 and tinted foundations with an SPF up to 50+. These products must also meet certain criteria (such as not containing ingredients included in the Poisons Standard and compliance with the 2021 Sunscreen Standard). Ingredients in sunscreen products that are not considered to be therapeutic goods, are regulated under the Australian Industrial Chemicals Introduction Scheme (AICIS).

All therapeutic sunscreens must be included in the Australian Register of Therapeutic Goods (ARTG) to be supplied, imported, or exported in Australia. Most sunscreens are eligible for **listing** in the ARTG, in accordance with the criteria of Schedule 4, item 7 of the Therapeutic Goods Regulations 1990 (the Regulations), excerpt below:

| Item No. | Therapeutic goods |
|---|---|
| 7 | sunscreen preparations for dermal application, if:<br>(a) the claimed sun protection factor has been established by testing according to the method described in Australian/New Zealand Standard AS/NZS 2604:2021, Sunscreen products - Evaluation and classification, published jointly by, or on behalf of, Standards Australia and Standards New Zealand, as in force from time to time; and<br>(b) the performance statements and markings on the label comply with that Standard; and<br>(c) the sunscreen preparation only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act; and<br>(d) if a determination under paragraph 26BB(1)(b) of the Act specifies requirements in relation to ingredients being contained in the sunscreen preparation—none of the requirements have been contravened; and<br>(e) the sunscreen preparation only has indications that are covered by a determination under paragraph 26BF(1)(a) of the Act; and<br>(f) if a determination under paragraph 26BF(1)(b) of the Act specifies requirements in relation to the indications—none of the requirements have been contravened |

The TGA regulates therapeutic sunscreens by ensuring they are safe, efficacious and of appropriate quality. Before a sunscreen product can be marketed and supplied to consumers in Australia, the TGA must have approved its ingredients and their maximum safe concentration. Sponsors (who are product owners or manufacturers) are legally bound to adhere to these TGA-mandated concentration limits.

Listed therapeutic sunscreens are not pre-market evaluated by the TGA. Instead, they are included in the ARTG under section 26A of the Act, based on a number of sponsor certifications that their therapeutic good meets all legislative requirements, for example, they can only include TGA pre-approved ingredients and indications. Listed sunscreens must also comply with the 2021 Sunscreen Standard (which is adopted by the TGA by reference in the Regulations and the Excluded Goods Determination).

It is the legal responsibility of each sponsor to ensure that their sunscreen is safe for the purposes for which it is to be used. Listed therapeutic sunscreens are also required to be manufactured under the principles of Good Manufacturing Practice, and sponsors must have an appropriate system of pharmacovigilance and report to the TGA adverse reactions experienced by users. The requirements for therapeutic sunscreens are described in the Australian Regulatory Guidelines for Sunscreens (ARGS).

If a sunscreen does not meet the eligibility criteria for listing in the ARTG provided by Schedule 4 to the Regulations (e.g. it contains ingredients that are not permitted for use in listed medicines), then it is required to be included in the ARTG as a registered good and undergo a full TGA pre-market evaluation of safety, quality, and efficacy.

Many overseas jurisdictions (such as in the European Union) regulate sunscreens as cosmetics, and only permit them to make cosmetic claims. However, in Australia, therapeutic sunscreens providing SPF 30 or higher can make high-level therapeutic indications referring to the prevention of skin cancer, while cosmetic sunscreens cannot make such claims.

# How ingredients in therapeutic sunscreens are regulated

Sponsors of therapeutic sunscreens can only use pre-approved low risk ingredients included in the Therapeutic Goods (Permissible Ingredients) Determination for listed medicines. Any new ingredients must be evaluated for safety and quality and assessed as being low risk by the TGA before it can be added to this list.

The safety data for new ingredients must be comprehensive, covering both short-term (acute) and long-term (chronic) effects on human health and safety from exposure to the ingredients. The ARGS specify that sponsors must consider the safety of the substance across different population groups, as sunscreens are used by individuals of all ages, genders, and could be used frequently

(daily) for extended periods.

The ARGS also refer to the Application requirements for new substances in listed medicines (ARNS) for more detailed guidance. The ARNS provides guidance for assessing toxicological data for substances for dermal use, such as sunscreens, and references methods in the Notes of guidance for the testing of cosmetic ingredients and their risk assessment, 11th revision (SCCS 2021). It also states that substances not restricted to adult use must discuss the relevance of Margin of Safety (MoS) calculations for children, considering the difference in skin surface area to body weight ratio. Additionally, the ARNS mentions that limited safety data is required if a substance is not absorbed beyond the stratum corneum and does not react with the skin in a hazardous way.

This process allows the TGA to ascertain whether a substance presents a sufficiently low risk to be permissible for use in listed medicines.

## How risk for ingredients is evaluated

Risk assessments for sunscreen ingredients typically focus on long-term exposure to the ingredient, but they also address acute safety concerns like potential skin irritation. The risks associated with use of ingredients are characterised by calculating the Margin of Safety (MoS), which compares the associated (health) hazards to the expected systemic (or internal) exposure of the ingredient. The MoS calculation helps ascertain the maximum safe concentration of an ingredient. The internal exposure dose is referred to as the Systemic Exposure Dose or 'SED', which is the amount of an ingredient absorbed through the skin into the systemic circulation.

When considering the risks to human health and safety from the use of substances in therapeutic goods, including sunscreens, it is essential to consider their use in the context of hazard and exposure. The hazard of a substance is defined by its intrinsic toxicity, characterised by the dosage and its short-term or long-term adverse effects on biological systems, with a critical factor being the identification of a toxicological threshold known as the 'No Observed Adverse Effect Level' (NOAEL) where no adverse effects are observed.

### *Margin of safety*

When considering the risks to human health and safety from a wide range of substances, a MoS approach is used by many regulators. The MoS compares the expected SED of a substance within the human population to a toxicological threshold, known as the 'No Observed Adverse Effect Level' (NOAEL). The NOAEL is the level at which no specific adverse effects were observed in humans or animals, adjusted for body weight. Typically, the NOAEL is derived from long-term, repeat-dose toxicity studies in animals. As such, the MoS value indicates the likelihood of an adverse health effect occurring under specific exposure conditions.

To correct for the uncertainty in the data, the internationally accepted methodology utilises a correction factor of 10 to account for interspecies differences between animals and humans, and a further correction factor of 10 for intraspecies differences to account for variations in the human population. These factors are multiplied together to arrive at a value of 100. Margins of Safety below 100 are generally considered unacceptable[10]. In addition, as the MoS increases, the potential risk decreases.

Determining the adequacy of the MoS requires expert judgment, which is typically exercised on a case-by-case basis. This judgment should account for uncertainties in the risk assessment process, such as data completeness and quality, the nature and severity of the adverse effects, and intra/inter species variability.

[10] The acceptable MoS cutoff should reflect the quality of safety data available. Acceptance of lower MoS values may be deemed appropriate when the NOAEL is based upon human toxicological data. Conversely, a requirement for higher MoS values may arise such as, in instances where the duration of the toxicological study does not adequately reflect the intended duration of exposure.

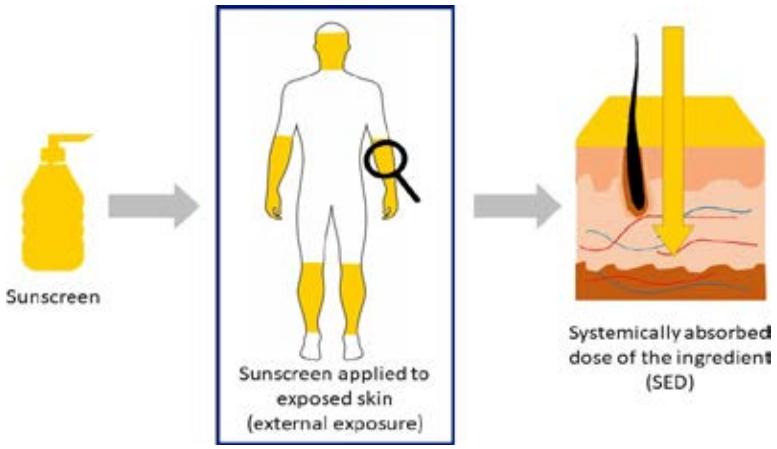
The following formula is used to calculate the MoS:

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)}$$

### *Systematic Exposure Dose*

Determining the SED is based on how much sunscreen is applied to the skin daily (i.e. the external exposure dose), which is difficult to estimate as sunscreen usage varies greatly among individuals. Figure 1 describes the relationship between the external exposure and systemic exposure.

**Figure 1: Relationship between sunscreen applied externally to skin and systemic exposure**




Exposure is the identification and characterisation of the contact between a product or substance and the host, in this case humans. For dermally applied products, the exposure can be either local or both local and systemic.

There are 2 broad areas of risk associated with dermally applied products, including sunscreens:

1. Adverse effects at or around the site of application/administration e.g. irritation and inflammation.
2. Adverse effects related to systemic effects following distribution of substances internally via ingestion, inhalation, or penetration/absorption though the skin, eyes, and other areas of the body.

Local intolerance of a dermally applied product may be thought as time-limited and self-identifiable, i.e. a product can be removed (washed) off the skin or flushed from the eyes, (skin surface removal/sloughing) and a person could readily identify irritation to the eyes, skin and mucosal surfaces.

On the other hand, the adverse effects of the product on the human body when distributed internally to other tissues and organs and for varying periods of time may not be immediately obvious or not become apparent for many months or years after exposure. The TGA considers the systemic exposure as a critical determinant when considering the inherent risks from contact with dermally applied products, including sunscreens.

## Factors affecting exposure

Exposure can be characterised by the site of contact e.g. dermally applied sunscreen on skin; the period of time that the contact was in place; and whether that contact was a singular event, regular exposure over a short-term, e.g. hours or days, or regular exposure over a long-term, e.g. weeks or years. Exposure also characterises the level/concentration of specific substances at the site of contact and their distribution to other areas within the human body.

All manner of substances may be absorbed by the human body after contact or application (this is known as systemic exposure). How much is absorbed into the body is dependent on a number of

factors related to the human body interface and the substance itself (see Table 2). Any systemic exposure of a substance, and adverse effects related to systemic effects must be considered when assessing the risk, and subsequent suitability for the use of a substance in humans.

**Table 2: Factors affecting absorption and systemic distribution of dermally applied substances**

| Human body interface | Substance |
|---|---|
| Route of exposure: skin, eyes, nasal, respiratory, gastrointestinal, etc.<br>Integrity of the interface: irritated, inflamed, abraded, etc.<br>pH of the interface.<br>Contact time with the product or substance.<br>Enzymatic metabolism (e.g. metabolism into smaller molecules) or clearance of the substance at the site of contact.<br>Movement of the substance from the site of contact e.g. washing of the skin; flushing of the eyes; aspiration by the lungs; vomiting, transit and/or enzymatic degradation in the gastrointestinal tract following ingestion. | Molecular weight pKa<br>Lipophilicity (log KOW)<br>Photoreactivity/stability<br>Co-formulation with other substances that can affect absorption e.g. solvents that alter skin permeability.<br>Concentration<br>Vapour pressure |

In general, small and lipophilic substances, in contrast to large and hydrophilic substances, are more likely to penetrate the skin and distribute systemically around the body. While some medicines are formulated to be absorbed into the body (e.g. transdermal patches), sunscreens are not, as their primary role is to provide either a physical barrier (reflector) to UVR e.g. zinc oxide and titanium dioxide, or absorb the UVR e.g. avobenzone and octocrylene, and prevent the penetration of this radiation through to deeper layers of the skin.

## Different approaches for assessing sunscreen exposure

Risk assessments for sunscreen ingredient safety that may end up being absorbed into the body, can employ various methodologies to calculate the amount of sunscreen applied to the skin. Some of these assessments may be excessively conservative or fail to consider the unique Australian context.

Historically, risk assessments and approvals of ingredients by the TGA have been conducted on a case-by-case basis, with regulatory guidelines evolving over time. These assessments consider the general toxicological profile and intended use of the ingredient. The assessments have primarily relied on data provided by the applicant, along with considerations of precedents set by international regulatory bodies. The variance in exposure calculation methods can result in regulatory inconsistencies and uncertainties for applicants seeking to introduce new ingredients to the market.

A number of new sunscreen ingredient applications have used exposure models from the SCCS or the then Scientific Committee on Cosmetic and Non-Food Products intended for Consumers (SCCNFP).

The TGA utilises the calculation methods described by the SCCS to calculate the SED in cosmetic products, in its calculations to determine the SED of dermally applied products, including sunscreen products.

The current SCCS models are based on European and other country usage patterns and do not account for Australian use patterns, or the amount of sunscreen application required to achieve the labelled Sun Protection Factor (SPF)[11] rating. While the SCCS uses a 60 kg bodyweight estimate in their calculations, the TGA has historically used a more conservative bodyweight estimate of 50 kg in some assessments. Further, the SCCS method shows a substantial disparity in the risk assessment calculations depending on whether data for dermal absorption of an ingredient is reported in µg/cm² or as a percentage.

Some assessments have adopted a higher exposure using a sunscreen application rate of 2 mg/cm²

[11] The SPF is the level of protection a sunscreen offers against sunburn. It relates to the amount of time it takes for redness to appear on the skin compared to when no sunscreen is applied.

than the SCCS approach which is based on studies that observed varying rates ranging from 0.5-1.3 mg/cm$^2$ (p 85, SCCS 2021). Other approaches have been based on the Cancer Council Australia's guidelines of reapplying sunscreen every 2 hours for a full-body application of 35 mL for a full day. The type of information that is presented by the applicant can also contribute to inconsistent assessments.

A standardised, evidence-based approach is essential for regulatory certainty and to ensure that sunscreens are safe, effective, and reflective of actual usage patterns in Australia, rather than relying on different approaches or international assessment models. This will provide a consistent framework for evaluating the safety of therapeutic sunscreen ingredients, aligning with Australian conditions and consumer practices.

## Sunscreen use by the general Australian population

Actual use may not always align with recommendations for how sunscreens are to be used effectively. Further, different methods for calculating the external exposure component may not fully capture Australian usage patterns. A standardised, evidence-based approach is required to calculate the external exposure of a sunscreen that considers the diverse ways Australians use sunscreen and ensures a realistic and safe framework for ingredient evaluation.

National Sun Protection Surveys conducted by Cancer Council Australia captures Australian adults' and adolescents' sun protection behaviours on summer weekends in 2003-2017. Consistently over the years the surveys were conducted, more than 40% of adults and more than 25% of adolescents used 2 or more sun protection methods, such as sunscreen (Cancer Australia 2019)[12]. However, the percentage of people who use sunscreen as one of the sun protection methods was not reported in these surveys.

The most recent representative survey prepared for Cancer Council Australia of Australian adolescents' and adults' sun protection behaviours in 2016-17 found that on a summer weekend the most common sun protective behaviour used by adolescents was using sunscreen with an SPF of at least 15 (40%) and the most common sun protective behaviours among adults were wearing sunglasses (61%), wearing a hat (49%), and using sunscreen with SPF 15 or higher (42%) (Tabbakh and Dobbinson 2018).

A survey conducted by Cancer Council Victoria of Melbourne residents' sun-related attitudes and behaviour over 3 decades, between 1987 and 2017, shows a significant and sustained improvement in sun protection behaviour, including increased sunscreen use, after the implementation of the SunSmart program. The timing and size of the shift in preventive behaviours implies that Cancer Council Victoria's SunSmart campaign is likely to have contributed to the reduced incidence in melanoma among younger cohorts (Tabbakh et al. 2019). Conversely, a systematic review exploring the use of sun-protection by outdoor sporting participants in Australasia concluded that adequate sun-protective behaviours are lacking despite 40 years of 'Slip Slop Slap' health promotion (Morton et al. 2023).

A study of adults who participated in a skin cancer prevention trial between 1992 and 1996, found that 56% of the eligible participants applied sunscreen at least 5 days per week, although 27% used sunscreen infrequently at 2 or fewer days per week (Neale et al. 2002). Almost 50% of the participants who reported less than daily sunscreen use stated that they did not think sunscreen application was necessary given the weather conditions or their planned activities. Of these respondents, 45% reported that they generally spent almost no time outdoors during the day.

A survey conducted on 670 beachgoers in the Newcastle district found that sunscreen was the most frequently used form of sun protection (Foot et al. 1993). Among the participants, 82% applied sunscreen to at least one body area. Among these participants, 69% had applied sunscreen with an SPF value higher than 15. The authors also reported that children under the age of 15 years were more likely to have used sunscreen compared to the older age groups.

[12] See Table 3 and 4 under the 'About the data' tab.

Queensland preventive health telephone surveys (QPHS 2023)[13] conducted by Queensland Health captured summer sun protection habits of 12,500 adults and the parents of 2,500 children aged 5 through 17 years. Based on the '*Sunburn and protection*' data reported in the Queensland Survey Analytic System, just over 20% of adults were using, presumably, combined sun protection methods of '*broad brimmed hat, SPF 30+* [sunscreen], *clothing*' in summer between 2010 and 2020. However, the percentage of adults using sunscreen as one of the sun protection methods was not reported.

The Cancer Council Australia has advised that recent research suggests men are less likely than women to use sun protection (Cancer Council Australia 2022). Almost half (47%) of men reported they often or always spent time outdoors during peak UVR hours during summer. Less than one third (29%) of men reported using sunscreen (broad-spectrum with SPF 30 or higher) often or always during peak UVR hours during summer. Less than half (49%) of men reported often or always seeking shade to protect themselves from the sun during peak UVR hours during summer. More than half of respondents (55%) reported being sunburnt at least once during the summer, with the most common activity being during a walk, jog or run (15%).

## Sunscreen use in children

A multi-year survey reported child-related sun protection practices from 2008, 2013 and 2018, covering 3,243 early-childhood services (i.e. childcare and/or pre-education services for infants and children aged ≤5 years) across Australia (Hunkin and Morris 2020). The authors reported significant increases over the last decade in the proportion of services requiring the use of sun-protective hats, sunscreen and protective clothing, as well as those services supplying sunscreen (98.4% of the services required the use of sunscreen in 2018). The proportion of services applying sunscreen to children 15-20 minutes before going outside and re-applying sunscreen every 2 hours while outdoors also significantly increased (in 2018, 68.3% of services required sunscreen to be applied regularly, every 2 hours if outdoors). It is noted that the percentage of services that required children to wear sun-protective clothing outside significantly increased from 68% (2008) to 88.8% (2018), however, the percentage of services requiring children to wear long sleeves significantly decreased from 45.1% (2008) to 17.9% (2018). The percentage of services requiring children to wear longer shorts/skirts remained below 30% throughout the survey years. The authors suggested that suboptimal UVR protection can result from incorrect sunscreen application in terms of amount used, time of application (relative to sun exposure) and reapplication, and therefore, appropriate sunscreen application techniques are an important target for future promotion efforts.

The unpublished report of 1,189 Australian early childhood centres surveyed in the 2018 National Early Childhood Sun Protection Policy and Practice Survey (Cancer Council SA 2018), which was the most recent survey data analysed by Hunkin and Morris (2020), reported further information on sunscreen use practices in early childhood centres. The report indicated a trend in increasing sunscreen practices in children. In 2018 most services required children to wear sunscreen all year, and more services applied sunscreen more frequently throughout the day, and required sunscreen when the UV index was 3 or more, rather than only part of the year. The data showed that in 2018, 49% of services across Australia applied sunscreen to children twice a day, 26% 3 times a day, and 11% more than 3 times. Western Australia had higher rates, with 40% of centres applying sunscreen 3 times daily and 20% more than 3 times. Between 2008 and 2018, there was a significant increase in the number of services providing sunscreen for children, promoting self-application, and encouraging application by parents or caregivers. There was also a rise in the practice of applying sunscreen 15-20 minutes before outdoor activities, assigning staff the responsibility of applying sunscreen to children, and regularly reapplying sunscreen. Conversely, there was a decline in the number of services that encouraged parents to provide sunscreen for their children. In addition, over 99% of services enforced hat wearing for children and 98% for staff members. Most services followed a policy of taking infants (under 12 months) outdoors only in shaded areas (71%), while 22% limited the duration of outdoor time for this age group. The use of UV levels as a criterion for implementing sun protection measures during certain times of the year

[13] QPHS survey result can be visualised in Queensland survey analytic system (QSAS)

increased to 61% in 2018, up from 35% in 2008. These findings underscore the evolving practices in early childhood centres to enhance sun protection for children, reflecting a growing awareness and implementation of recommended sunscreen use.

In a survey conducted for 187 childcare services in the Hunter region, 150 centres (87%) reported that the centre's policy required children to wear hats, and 122 (71%) required sunscreen be applied to children before outdoor play (Parkinson et al. 2003). However, the self-reported sun protection practices were lower, and 36% of children wore a hat and 57% applied sunscreen before outdoor play.

The Queensland QPHS survey conducted in 2020 found 74.9% of children aged 5-7 frequently use sunscreens with SPF 30+ (Queensland Government 2023)[14]. This percentage gradually decreases with increasing age, as 49.3% of children aged 16-17 frequently use sunscreens. Remoteness and socioeconomic status also impact sunscreen use. Children from remote areas or from disadvantaged socioeconomic backgrounds are less likely to use sunscreen frequently. The survey also found that 16% of children apply sunscreen as part of the morning routine[15].

A study conducted with children aged 5-12 years in Queensland found that children in the youngest school grades (1 and 2) applied significantly more sunscreen than the older children (Diaz et al. 2012). The authors recommended that educational interventions may help to improve sunscreen application thickness to maximise the protection received from sunscreen. The authors also commented that sunscreen is often the only form of sun protection used by children, therefore, children may be less well protected from the sun than parents might expect.

A survey conducted with 3,655 Queensland students (in grades 7, 9 and 11) reported that negative views of sun protection measures were associated with poorer sun protective behaviour; this association was strongest among older students and in larger schools (Balanda et al. 1999). Similarly, lower perceived parental sun protective behaviour was associated with poorer sun protective behaviours and older students had poorer sun protective behaviours than younger students.

## Sunscreen use by outdoor workers

An unpublished independent report commissioned by Safe Work Australia[16] conducted between January and July 2008 that comprised 4,500 telephone interviews with indoor and outdoor workers in all Australian industries, investigated the exposure to direct sunlight and the control measures provided in workplaces relating to direct sunlight exposure. Workers in northern states (QLD, NT, WA) exhibiting a 37% higher probability of high-level exposure to direct sunlight compared to southern states (NSW, ACT, SA, VIC, TAS). Male workers were 2.9 times more likely to be exposed than female workers. The disparity was more pronounced within industry sectors, with outdoor workers facing considerably higher exposure odds, being 18 times greater in agriculture, forestry, and fishing, and 8.8 times greater in construction, relative to manufacturing. The average daily exposure duration exceeded 4 hours for outdoor workers, with those in agriculture and construction experiencing upwards of 5.5 hours. Most common forms of protection were sunscreen, hats, or protective clothing. Sunscreen was reported to be provided by over half of the workers in most industries. The likelihood of sunscreen provision was 1.7 times higher in agriculture, forestry, and fishing (69% of workers provided with sunscreen), 2.4 times higher in construction (75**%**), and 6.2 times higher in government administration and defence (91%) compared to manufacturing (58%). Protective clothing followed a similar trend, with 1.9 times higher provision in construction (76% of workers provided with protective clothing) and 4.1 times higher in government administration and defence (87%) compared to manufacturing. Notably, despite the high exposure risk in agriculture, forestry, and fishing, only 68% of workers reported receiving protective clothing. The report concluded that there is limited evidence that workers exposed to longer durations of UVR are more likely to have access to protective controls than workers with a low level of exposure.

[14] 'Prevalence table' tab of Figure 3: Characteristics of sunburn and sun safety of Queensland children
[15] 'Introduction' tab of Figure 3: Characteristics of sunburn and sun safety of Queensland children
[16] Report provided to the TGA by Safe Work Australia

Another study by Girgis and colleagues investigated 184 outdoor workers' sun protection behaviour when outdoors between 11 am and 3 pm when there was no rain (Girgis et al. 1994). A body region was considered adequately protected if it was fully covered by clothing/hat or shaded at the time of the interview, and/or if sunscreen with an SPF 15 or higher had been applied to that region. Participants who had more than 75% of the body protected were classified as having high protection. The authors reported more than 49% participants used high level sun protection; however, the sunscreen use by outdoor workers was not reported.

### Application thickness of sunscreens

There is some limited contemporary research indicating that Australians apply, on average, a thickness that was less than the 2 mg/cm$^2$ sunscreen needed to achieve the labelled SPF rating. The amount of sunscreen used also depends on the formulation and dispenser type, for example roll-on versus pump-pack (Diaz et al. 2012; Neale et al. 2002) and could be influenced by how much the user perceives needs to be applied based on its visual appearance and feel after application. While research indicates an approximate average application thickness between 0.5 mg/cm$^2$ and 0.99 mg/cm$^2$ (Diaz et al. 2012; Neale et al. 2002) and Diaz et al. commented that an application thickness of 2 mg/cm$^2$ in children was infeasible, both studies report that some participants actually applied the correct thickness of 2 mg/cm$^2$ or more. Further, another Australian study using spectrophotometric analysis estimated an average application thickness of 1.4 mg/cm$^2$, with some participants also meeting the ideal application rate of 2 mg/cm$^2$ (Bauer et al. 2010).

## Correct sunscreen application

The level of protection provided by sunscreens, and therefore the ability to reduce the risk of skin cancer, is determined not only by the labelled sun protection factor (SPF)[17] rating but also by the amount of product applied and its conditions of use. As such, it is important they are safe and effective for their intended uses. The effectiveness is significantly reduced by inadequate application, infrequent reapplication, and loss of product due to sweat, swimming, or friction from clothing or towel drying.

Most people do not apply enough sunscreen or reapply frequently enough which can result in an SPF that is 20-50% less than what is specified on the product label (Diaz et al. 2012; Stokes and Diffey 1997).

### Current evidence-based sunscreen use guidelines

In the 1960s the risks of overexposure to UVR were first identified in Australia. Twenty years later, the iconic "Slip! Slop! Slap!" campaign was launched in 1980 to raise awareness of the dangers of UV, featuring Sid the Seagull. This campaign is credited with playing a key role in changing sun protection attitudes and behaviour in Australia. In 2007, the messaging was updated to "Slip, Slop, Slap, Seek, Slide", with which many Australians are familiar with.

The Australian Government has delivered a National Skin Cancer Prevention Campaign in partnership with Cancer Council Australia each summer since 2021-22. State and territory governments also fund skin cancer prevention activities, as do a number of non-government organisations. Funding of $15 million has been provided in the May 2024 Budget for a national skin cancer prevention campaign targeting groups most at risk, including men over 40 and young adults with activity to occur over the 2024-26 summers.

As the amount of sun protection is based on the amount of sunscreen applied, there is a concerted effort from government, researchers and other organisations through education and campaigns (such as the Cancer Council Australia's well-known SunSmart program (Cancer Council Australia n.d. - a) to encourage the correct application of sunscreen. For example, leading Australian

[17] The SPF rating serves as a guide for consumers, indicating the level of protection a sunscreen offers against sunburn. It assists individuals to choose a product that aligns with their skin's sensitivity and expected sun exposure.

organisations, including the Cancer Council Australia (2024a), Melanoma Institute Australia (n.d.), Australasian College of Dermatologists (2019), Safe Work Australia (2019), and Surf Life Saving Australia (2006), provide evidence-based recommendations on proper sunscreen usage to ensure effective sun protection. Consumers expect sunscreens to be safe for daily use in Australia (Cancer Council Australia 2017).

The Cancer Council Australia (n.d. - b) recommends adults use a teaspoon for the face, neck and ears; a teaspoon for each arm and leg; and a teaspoon each for the front and back of the body. It is also recommended to reapply every 2 hours or after activities that may remove the product, such as swimming, sweating or towel drying (Cancer Council Queensland n.d.). The Cancer Council Australia does not recommend sunscreen as the only method of protection even if the UV is 3 or above every day of the year and encourage the five forms of sun protection:

- slipping on sun protective clothing
- slopping on SPF 30 or above broad-spectrum water-resistant sunscreen
- slapping on a broad brim hat
- seeking shade when possible
- sliding on sunglasses.

In the 2023 position statement by Australian Skin and Skin Cancer Research Centre (ASSC) aimed at balancing the risks and benefits of sun exposure, it is recommended that sun protection behaviour should be tailored to the individual's risk of skin cancer (ASSC 2023). People who are at high risk of skin cancer (i.e. very pale skin and/or olive/pale brown skin but with other risk factors) are advised to adopt an extremely cautious approach to sun exposure including avoiding time outdoors when the UV index is ≥3. On days when the UV index is forecast to reach ≥3, irrespective of the length of time, sunscreen of at least SPF 30 should be used in the mornings as part of the usual daily routine and applied to all parts of the body not covered by clothing. Sun protection should also be used if these people planned to spend >2 hours (cumulatively across the day) outdoors when the UV index is between 1 and 3, and outdoor workers always use sun protection, irrespective of the UV index (ASSC 2023).

Sunscreen, often viewed as a protective measure for prolonged sun exposure during outdoor activities, but also the last line of UVR defence, is equally essential for daily protection against the often-overlooked incidental UV exposure that occurs during everyday tasks such as running errands or commuting. In 2019, an Australian and New Zealand evidence-based consensus statement was published recommending routine sunscreen application for adults and children on body parts not covered by clothing when the UV index is predicted to be 3 or above irrespective of their anticipated activities (Whiteman et al. 2019). This recommendation aims to reduce the incidence of skin cancer by accounting for incidental UV exposure resulting in cumulative skin damage, such as from everyday activities such as shopping, travelling to work, or household chores.

The Australian and New Zealand evidence-based consensus statement on when to apply sunscreen is relevant year-round for parts of Australia where the UV index consistently exceeds 3, such as Darwin, Brisbane, and Perth (Table 3) and where the UV index reaches above 3 between 11 am and 1 pm (Figure 2). Darwin for instance has a very high average UV index at solar noon above 8 every month of the year; however, the recommendation may not apply to lower latitudes where the sun is lower in the sky such as Kingston in Tasmania during the 4 months it experiences an average UV index below 3 (ARPANSA 2024).

**Table 3: Average daily maximum UV index for Australia by month and city, reproduced from Whiteman et al. (2019)**

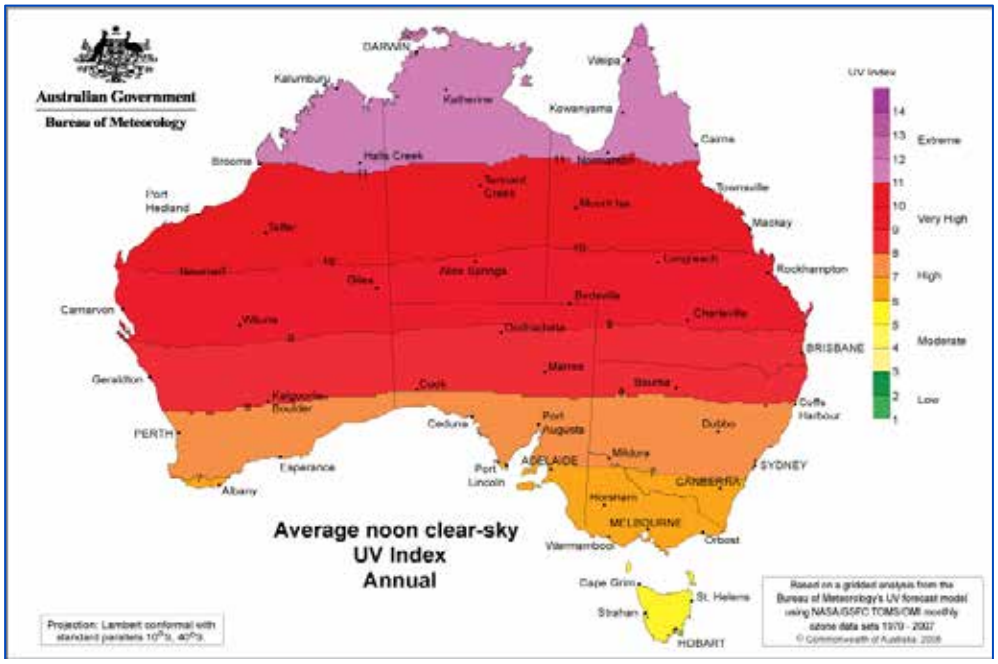
**Table 1: Average daily maximum UV index for Australia and New Zealand, by month and city**

| City | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct | Nov | Dec |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Australia** | | | | | | | | | | | | |
| Darwin | 12 | 13 | 13 | 11 | 9 | 8 | 9 | 10 | 12 | 13 | 12 | 12 |
| Brisbane | 12 | 11 | 10 | 7 | 5 | 4 | 4 | 5 | 7 | 9 | 11 | 11 |
| Perth | 12 | 11 | 9 | 6 | 4 | 3 | 3 | 4 | 6 | 8 | 10 | 11 |
| Sydney | 11 | 10 | 8 | 5 | 3 | 2 | 3 | 4 | 5 | 7 | 9 | 10 |
| Canberra | 11 | 8 | 7 | 5 | 3 | 2 | 2 | 3 | 5 | 7 | 9 | 11 |
| Adelaide | 11 | 10 | 8 | 5 | 3 | 2 | 2 | 3 | 5 | 7 | 9 | 11 |
| Melbourne | 10 | 9 | 7 | 4 | 2 | 2 | 2 | 3 | 4 | 6 | 8 | 10 |
| Hobart | 8 | 7 | 4 | 3 | 1 | 1 | 1 | 2 | 3 | 4 | 6 | 7 |
| **New Zealand** | | | | | | | | | | | | |
| Auckland | 10 | 8 | 7 | 4 | 2 | 1 | 2 | 2 | 3 | 6 | 8 | 9 |
| Wellington | 9 | 8 | 6 | 3 | 1 | 1 | 1 | 2 | 2 | 5 | 7 | 8 |
| Christchurch | 8 | 7 | 5 | 2 | 1 | 1 | 1 | 1 | 2 | 4 | 7 | 8 |
| Invercargill | 7 | 6 | 4 | 2 | 1 | 0 | 0 | 1 | 2 | 3 | 5 | 6 |

*Notes:*

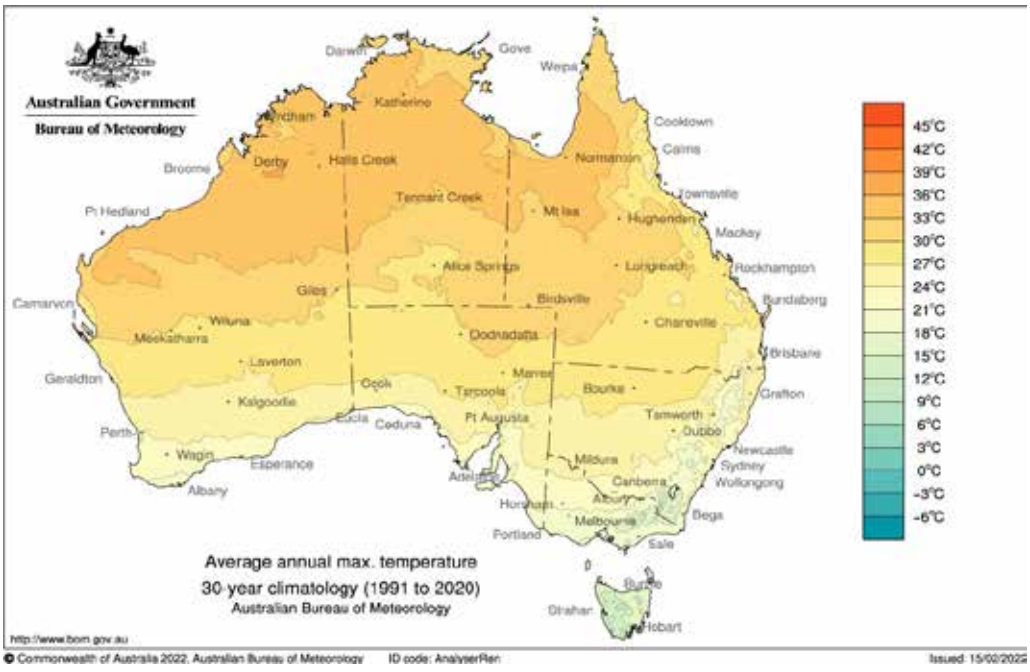
*Sunscreen should be applied to exposed body sites daily when the maximum UV index is forecast to reach 3 or more. Shaded cells show months when the average maximum UV index does not reach 3.*

**Figure 2: Average annual UV Index for Australia, for 1979-2007 under cloud-free conditions at local noon. These values are also representative of UV Index expected between 11 am and 1 pm local time (12 pm and 2 pm daylight saving time) under clear skies (BOM 2024a).**




Northern regions of Australia are closer to the equator and typically have warmer climates (Figure 3) that encourage lighter clothing and increased time outdoors. With last year ranking as Australia's equal eighth-warmest on record (BOM 2024b), and the projected trend towards warmer climates continuing (BOM 2024c), sunscreen will continue to be an important sun protection measure in the future. This geographical variance in UV exposure and climate conditions highlights the importance of a model that ensures adequate protection for all Australians, regardless of their location.

**Figure 3: Average annual maximum temperatures over the period 1991 to 2020 (BOM 2024d).**




## How sunscreens should be used to achieve the labelled SPF rating

Therapeutic sunscreens must comply with the requirements of the *Australian/New Zealand Standard: Sunscreen products – Evaluation and classification (AS/NZS 2604:2021) (amended) (the Australian Sunscreen Standard*). The *Australian Sunscreen Standard* was adopted into therapeutic goods legislation on 1 July 2024.

The standard acknowledges that in circumstances where the dosage used in the measurement of the SPF (2 mg/cm$^2$) is not applied, the expected sun protection will not be achieved. This is supported by research that demonstrates reduced application thickness exponentially decreases the SPF (Faurschou and Wulf 2007; Schalka et al. 2009). The standard also requires primary sunscreens to be labelled with clear and appropriate directions so the labelled claims will be achieved, advising that the instructions should state the product should be applied generously. The SunSmart 2024[18] guidelines also recommend applying more sunscreen than one might think is necessary to achieve adequate application.

**Sunscreen for infants (birth to 12 months)**

Both the Australasian College of Dermatologists and Cancer Council Australia advise that infants under 12 months should not be exposed to direct sunlight when the UV Index is 3 or higher and sunscreen is not recommended for infants under 6 months (Australasian College of Dermatologists 2018 and Cancer Council Australia 2024b). For infants over 6 months, sunscreen can be applied to small areas of skin not covered by clothing or hats, but it should be considered as the last line of defence after other sun protection measures, including covering as much skin as possible with clothing.

## Challenge of aligning recommended sunscreen application with the risk assessment

Reflecting on the complexities involved, it is evident that calculating sunscreen exposure to

[18] SunSmart (2024). Protect your skin - SunSmart. [online] Available at: https://www.sunsmart.com.au/protect-your-skin#sunscreen. [Accessed 20 June 2024].

effectively cater to the diverse Australian population is a complicated task. That given, it is vital to integrate the expected sunscreen application practices, which align with the current Australian recommendations, into the risk assessment of sunscreen ingredients. Further, this assessment should take into account the concerted government and community efforts to refine sun protection behaviours, ensuring that the evaluations are prepared for future sunscreen usage trends. This ensures that sunscreens not only meet the protective needs of Australians but also adhere to public health directives, thereby reinforcing the safety and integrity of sunscreen products for all Australians.

# 1. What is the policy problem you are trying to solve and what data is available?

## The problem

The TGA regulates therapeutic sunscreens by ensuring they are safe, efficacious and of appropriate quality. Before a sunscreen product can be marketed and supplied to consumers in Australia, the TGA must have approved its ingredients and their maximum safe concentration. The TGA evaluates the safety of sunscreen ingredients based on the amount of sunscreen applied to the skin (i.e. external exposure).

Historically, risk assessments and approvals of ingredients by the TGA have been conducted on a case-by-case basis. These assessments consider the general toxicological profile and intended use of the ingredient. The assessments have primarily relied on data provided by the applicant, along with considerations of precedents set by international regulatory bodies.

Risk assessments for the safety of sunscreen ingredients that may be absorbed into the body can employ various methodologies to calculate the amount of sunscreen applied to the skin. Some of these assessments may be excessively conservative or fail to consider the unique Australian context. The variance in exposure calculation methods can result in regulatory inconsistencies and uncertainties for applicants seeking to introduce new ingredients to the market.

A number of new sunscreen ingredient applications have used exposure models from the SCCS or the then Scientific Committee on Cosmetic and Non-Food Products intended for Consumers (SCCNFP). The TGA utilises the calculation methods described by the SCCS to calculate the SED in cosmetic products, in its calculations to determine the SED of dermally applied products, including sunscreen products

The current SCCS models are based on European and other country usage patterns and do not account for Australian use patterns, or the amount of sunscreen application required to achieve the labelled SPF[19] rating. While the SCCS uses a 60 kg bodyweight estimate in their calculations, the TGA has historically used a more conservative bodyweight estimate of 50 kg in some assessments. Further, the SCCS method shows a substantial disparity in the risk assessment calculations depending on whether data for dermal absorption of an ingredient is reported in µg/cm² or as a percentage.

Some assessments have adopted a higher sunscreen application rate of 2 mg/cm2 compared to the SCCS approach, which is based on studies reporting varying rates from 0.5 to 1.3 mg/cm2 (SCCS 2021, p. 85). Other approaches have been based on the Cancer Council Australia's guidelines of reapplying sunscreen every 2 hours for a full-body application of 35 mL for a full day. The type of information that is presented by the applicant can also contribute to inconsistent assessments.

There is currently no model that accurately estimates how much sunscreen Australians are exposed to on a regular basis. There is little contemporary data on how much sunscreen Australians apply to

[19] The SPF is the level of protection a sunscreen offers against sunburn. It relates to the amount of time it takes for redness to appear on the skin compared to when no sunscreen is applied.

their skin and the amount used is variable and difficult to estimate as sunscreen usage varies greatly among individuals. Actual use may not always align with recommendations for how sunscreens are to be used effectively and different methods for calculating the external exposure may not fully capture Australian usage patterns.

TGA guidance does not provide a standard estimated daily sunscreen exposure value for sunscreen ingredient risk assessments for applications for new sunscreen ingredients. Subsequently, applicants for new ingredient evaluations differ on the methodology they use to estimate the daily sunscreen exposure and these existing approaches do not consider the Australian context.

A standardised, evidence-based approach is essential for regulatory certainty and to ensure that sunscreens are safe, effective, and reflective of actual usage patterns in Australia, rather than relying on different approaches or international assessment models. This will provide a consistent framework for evaluating the safety of therapeutic sunscreen ingredients, aligning with Australian conditions and consumer practices.

## Why it is a problem?

Recent international and domestic concerns relating to the safety of certain sunscreen active ingredients has identified the need for a consistent, fit-for-purpose approach to conduct risk assessments for these ingredients that provides industry certainty, and a consistent and reliable outcome that bolsters consumer confidence in the safety of Australian sunscreens and encourages sun protective behaviour.

Not having an Australian focused consistent approach to ingredient evaluations has resulted in the following problems:

- The absence of an agreed estimated daily sunscreen exposure value means there is no standardised method for evaluating sunscreen ingredients, potentially leading to discrepancies in risk assessments where some may be overly conservative, while others may not be conservative enough. This means the same ingredient could be approved or refused based on the same data.
- Regulatory inconsistencies lead to uncertainty for industry. This is problematic given the lengthy research and development process required to bring new ingredients to market, with tests that may need to be conducted at the proposed concentration for final products. Uncertainty about the concentration that may be approved by the TGA, based on the assessment methodology, could stifle innovation and the development of new sunscreen ingredients.
- Without an Australian accepted approach, evaluations are more prone to being challenged, leading to increased time and resources expended by all stakeholders in debating application decisions. This not only delays the introduction of new sunscreen ingredients but also burdens the regulatory process with unnecessary contention.
- Applicants may be required to provide scientifically robust arguments to support their chosen approach, which may not be supported by the TGA evaluator if not well-founded. Given the complexity of assessing sunscreen exposure, this could pose significant challenges and add unnecessary time and regulatory costs for new ingredient applicants.
- Some estimated daily sunscreen exposure values proposed by applicants, and those ultimately employed may not adequately reflect the unique Australian context, such as the higher levels of UV exposure and adherence to current evidence-based guidelines for effective sun protection. The methods employed may not account for Australian practices today for the most frequent sunscreen users.
- Sunscreen exposure considerations differ internationally, with the European SCCS estimating exposure model being one of the main approaches that is also utilised by applicants in Australia. However, this is based on data from research conducted in countries outside Australia. It is unclear if this would be relevant for the Australian context, given we have the highest rates of skin cancer in the world, a focus on public health messaging on the importance of using sunscreens, a

thinner ozone layer, and an outdoor lifestyle. Further, because of their public health importance, sunscreens that are primarily for prevention of skin cancer are regulated as therapeutic goods in Australia, while they are regulated as cosmetics in Europe which are not allowed to make the same claims.

- In addition, depending on the available data, the SCCS exposure calculation method can yield considerably different risk assessments for the same ingredient. This discrepancy could result in the same ingredient being approved under one set of data but rejected if presented in a different way. Such inconsistencies raise concerns about the appropriate calculation method for regulatory approvals and the potential for regulatory uncertainty, requiring expert judgement for which calculation method will be most suitable. The type of information that is presented by the applicant could also contribute to inconsistent assessments.

# Magnitude of the problem & costs of not doing anything

## Australian public

There have been increasing scientific concerns, both domestically and internationally, over long-term use risks of some sunscreen ingredients. In 2019, the US FDA indicated they would remove some sunscreen ingredients from their Generally Recognised as Safe and Effective (GRASE) list, while calling for more data. Similarly, the SCCS in Europe has deemed certain ingredients unsafe in sunscreens applied to the body in higher concentrations.

These international developments have the potential to negatively impact consumer confidence in the safety of sunscreens and reduce sun protective behaviours. This is of particular concern because exposure to UVR via sun exposure is estimated to cause around 95% of melanoma cases in Australia (Cancer Australia)[20]. Exposure to UVR is the main preventable cause of skin cancer and sunscreen is one important measure that Australian consumers can use to reduce their risk.

In response to international developments, the TGA is currently undertaking its own review of contemporary scientific literature on the safety of the active ingredients that are approved for use in sunscreens in Australia. In order to complete these reviews and determine the safe level of sunscreen ingredients in Australia, the TGA needs to put in place a consistent methodology to assess Australian exposure.

Completing these reviews using an evidence-based approach that is tailored for the Australian context, will maintain and increase consumers' confidence in the safety and efficacy of Australian sunscreens and assist in consumers adopting sun protection behaviour without fear or doubt.

## Industry

International concerns in relation to certain sunscreen ingredients has created uncertainty for the sunscreen industry about what action the TGA, and overseas regulators, may take in relation to these ingredients. Uncertainty affects the development of products for future release. Clarity is needed to provide industry with confidence to manufacture products that will be accepted by the TGA following its review.

Additionally, regulatory inconsistencies regarding the assessment of new ingredients lead to uncertainty for industry. This is problematic given the lengthy research and development process required to bring new ingredients to market, with tests that may need to be conducted at the proposed concentration for final products. Uncertainty about the concentration that may be approved by the TGA, based on the assessment methodology, could stifle innovation and the development of new sunscreen ingredients and formulations.

[20] https://ncci.canceraustralia.gov.au/prevention/sun-exposure/sunburn-and-sun-protection

## Government

A lack of consumer confidence in sunscreens (due to Australian sunscreens not being assessed to a consistent methodology) may result in reduced sun protection behaviour, an increase in skin cancer in the Australian population and increased pressure on the Australian healthcare system.

Skin cancers are responsible for the highest cancer-related health system expenditure at more than $1.6 billion, placing significant burden on Australia's healthcare system (Australian Institute of Health and Welfare, 2023[21]). Skin cancer is the most expensive cancer to treat in Australia – more than breast, prostate or lung cancer. Ongoing national investment in prevention, early detection and treatment is needed (Australasian College of Dermatologists, 2023)[22]. Sunscreen is an important part of skin cancer prevention and it is important that Australian consumers have confidence in the safety and efficacy of the sunscreens they use.

The Australian Government's commitment to reducing skin cancer's impact is evident in its longstanding investment in research and public health campaigns such as the National Skin Cancer Prevention Campaign to educate Australians on proper sunscreen use.

Investments in skin cancer prevention programs, which promote sunscreen use alongside other sun protection measures, bring strong returns on investment. Whiteman et al. (2019) state that daily sunscreen use produced substantial cost savings to government over a five-year period and long-term modelling. In Australia, for every dollar spent on skin cancer prevention programs/campaigns, there is an expected $3.20 return with a net social benefit of $1.43 billion. Using sun protection measures (including sunscreens) will likely reduce future health care spending, patient medical expenses and other societal costs. As such, having sunscreens that consumers are confident are safe for the Australian context are essential to recognising the health benefit of sunscreens and future health cost savings.

# 2. What are the objectives, why is government intervention needed & how will success be measured?

## Objectives of intervention

The objectives for establishing a robust method to approximate sunscreen exposure in Australia to calculate the maximum safe concentration of sunscreen ingredients are to:

1. **Ensure the safety of sunscreens for Australian consumers:**
    a. **Specific:** Enhance the safety reputation of Australian sunscreens.
    b. **Measurable:** Sunscreen active ingredients are safe at the levels they are permitted in sunscreens.
    c. **Achievable:** The model can be used to calculate the safe permitted level.
    d. **Realistic:** Promotes public health and safety by encouraging the use of sunscreens.
    e. **Time bound:** Over a 2-year period post-implementation.
2. **Enhance consumer safety and trust in sunscreens to promote sunscreen usage:**

[21] www.aihw.gov.au/reports/cancer/cancer-data-in-australia/contents/overview-of-cancer-in-australia-2023
[22] https://www.dermcoll.edu.au/wp-content/uploads/2023/09/ACD-Statement-Impact-of-skin-cancer-in-Australia-August-2023.pdf

a. **Specific:** Enhance the safety reputation of Australian sunscreens.

b. **Measurable:** Increased use of sunscreens by consumers.

c. **Achievable:** Ensure all sunscreens meet stringent safety standards and communicate these standards effectively to the public.

d. **Realistic:** Promotes public health and safety by encouraging the use of sunscreens.

e. **Time bound:** Over a 2-year period post-implementation.

3. **Increase regulatory certainty for sunscreen industry:**

a. **Specific:** Enhance regulatory efficiency and consistency through a risk based and data driven approach.

b. **Measurable:** Increase in positive feedback from stakeholders and reduction in applications being refused due to a lack of clarity regarding the assessment process.

c. **Achievable:** Based on key assumptions that changes would lead to a standardised, evidence-based methodology, that is practical for applicants and evaluators to assess ingredient risk.

d. **Realistic:** Feedback from industry is that this is feasible and appropriately risk based.

e. **Time bound:** Over a 2-year period.

The guiding principles to determine the preferred model are as follows:

1. **The model should be based on contemporary evidence-based information:**

a. **Specific:** The exposure model should consider demographic data for sunscreen users, such as children and adults in the context in which sunscreen is applied.

b. **Measurable:** Ensure the model has and includes all demographic groups and usage patterns specific to Australia.

c. **Achievable:** The model is practical and able to be utilised by ingredients applicants.

d. **Realistic:** Feedback from industry is that this is feasible and the TGA is adequately resourced to implement the changes.

e. **Time bound:** Over a 2-year period.

2. **The model should reflect correct usage directions for effective sun protection:**

a. **Specific:** Integrate evidence-based application guidelines to achieve the labelled SPF rating, ensuring that sunscreen ingredients are safe and effective when used as directed. It should be future proof where possible to account for future expected sunscreen use based on current and emerging evidence-based recommendations.

b. **Measurable:** Ensure the model has all demographic groups and usage patterns specific to Australia.

c. **Achievable:** The model is practical and able to be utilised by ingredients applicants and evaluators.

d. **Realistic:** Improves public health by reducing the incidence of skin cancer.

e. **Time bound:** Implemented end 2024.

3. **The Model should account for Australian usage and the highest realistic use-case:**

a. **Specific:** The model should account for sunscreen usage by the average Australian and those who use sunscreen more frequently, such as outdoor workers in northern Queensland, where the UV index is very high all year round. The model should consider the highest plausible sunscreen use throughout the year, for the most sensitive population.

b. **Measurable:** This approach ensures that the risk assessments for sunscreen ingredients, when based on the highest usage scenarios, will also guarantee safety for lower usage cases where less of the ingredient may be applied to the skin.

c. **Achievable:** The model is practical and able to be utilised by ingredient applicants and evaluators.

d. **Realistic:** the TGA is adequately resourced to implement the changes.

e. **Time bound:** Implemented end-2024.

# Why is Government intervention needed

Under the *Therapeutic Goods Act 1989* and supporting legislation, the TGA is responsible for the regulation of sunscreen products that are regulated as therapeutic goods.

For a product to be included in the ARTG and be able to be supplied in Australia, a sponsor must certify that their product meets all applicable legislative requirements which includes a certification that the product only uses pre-approved low risk ingredients included in the Therapeutic Goods (Permissible Ingredients) Determination for listed medicines. Any new ingredients must be evaluated for safety and quality and assessed as being low risk by the TGA before it can be added to this list.

The TGA has published guidance to assist applicants understand what is required to demonstrate that an ingredient is low risk. The safety data required for new ingredients is comprehensive, covering both short-term (acute) and long-term (chronic) effects on human health and safety from exposure to the ingredients. As the TGA is responsible for establishing what the requirements are to demonstrate that an ingredient is low risk, it follows that the TGA should be responsible for establishing a consistent methodology for ascertaining consumer sunscreen exposure and the safe levels of sunscreen ingredients.

The implementation of a consistent and transparent process for assessing the safety of sunscreen ingredients that aligns with Australian conditions and consumer practices, will offer regulatory certainty and a fair framework for industry applications. This will reinforce consumer expectations that sunscreens approved for use in Australia are safe to be used by everyone, no matter their age or outdoor activity.

A key assumption is that industry will accept the model and that it will be an improvement over the status quo. The TGA has collaborated with a diverse range of stakeholders throughout the process of developing the ASEM, further details are provided in Section 5. As a result of these extensive consultations and collaboration, the TGA does not anticipate any significant pushback on the proposal. This proactive collaboration has helped gain wide support for the model, as provided in stakeholder consultation feedback.

Potential barriers to government action may be that, as the compliance with the model will not be legislated, applicants could theoretically present a different, or equivalent model in the future that does not align with the guidance. However, this is unlikely as the development of the ASEM has required a considerable amount of consultation, collection of scientific evidence and data, and policy development. As such, the time and resources required to develop an alternative model, conduct research to support an alternative approach with strong evidence and reasoning, and gain stakeholder consensus, would be unrealistic to achieve for individuals. The TGA has the relevant skills and resourcing to develop and utilise the ASEM when undertaking risk assessments for new sunscreen active ingredients. The TGA has not identified any issues or limitation to undertaking this task. Further, the TGA established a 6-month Sunscreen Taskforce specifically to develop and

consult on the model, as such there do not appear to be any barriers or funding and resourcing constraints for the TGA to implement the model.

The exposure model is intended to align with current evidence-based sunscreen use guidelines and concerted efforts to encourage correct application of sunscreens, such as those described in the Australian Government's National Skin Cancer Prevention campaign, the Cancer Council Australia's SunSmart program, the 2023 position statement by Australian Skin and Skin Cancer Research Centre, the 2019 Australian and New Zealand evidence-based consensus statement on when to apply sunscreen, and many other organisations such as the Melanoma Institute Australia, Australasian College of Dermatologists, and Safe Work Australia.

A standardised, evidence-based approach is essential for regulatory certainty and to ensure that sunscreens are safe, effective, and reflective of actual usage patterns in Australia, rather than relying on different approaches or international assessment models. This will provide a consistent framework for evaluating the safety of therapeutic sunscreen ingredients, aligning with Australian conditions and consumer practices.

### Alternatives to government intervention

An alternative to government intervention would be to maintain the status quo, where sunscreen active ingredient risk assessments will be on a case-by-case basis, with the applicant able to use various approaches providing they can furnish an acceptable justification for their approach. However, as discussed under option 3, this approach will not provide consistency, transparency and certainty for industry and consumers.

Another alternative is that sunscreen stakeholders could develop a sunscreen exposure model. However, the ability for the various stakeholders to agree on an approach may be challenging, time consuming and not achievable. For example, it is likely that some stakeholders would propose a more conservative approach, whereas others may propose a less conservative approach. In addition, there may be challenges with the TGA requiring ingredient applicants to use the specific model that was developed by these applicants or their affiliated industry partners, and as such, consistency and transparency of ingredient evaluations is unlikely to be achieved.

## How success will be measured

The following measures will be used to determine the success of the adopted model:

### Monitoring of new ingredient applications

The TGA will monitor how may new sunscreen ingredient applications are received and compare this to application numbers prior to the adoption of the exposure model over the next 5 years, noting that application numbers can vary based on a range of other factors that may not be related to the exposure model. Higher application numbers could indicate more confidence in the regulatory assessment process.

### Applicant surveys

Applicants/agents will be asked to complete a short survey outlining their experience regarding the use of the new model, including questions in relation to decreased or increased effort to compile dossiers.

The TGA will consider any feedback from applicants for new ingredients regarding whether the guidance is clear about the risk assessment process and the adopted model is easy to understand and use.

### Stakeholder engagement/feedback:

Representatives of peak industry bodies will be asked to provide feedback at regular TGA industry

consultative forums.

Negative feedback could indicate the guidance requires revision to ensure the model is easy to use and supports ingredient applicants to understand the process. The aim will be to understand if the model has made the evaluation process clearer and easier to follow.

### Monitoring of overseas regulators and development of other models:

The TGA will continue to monitor developments with other overseas regulators (such as the SCCS and US FDA) on matters relating to safety of sunscreen ingredient assessments.

Any new models or risk assessment approaches will be considered and inform whether the adopted model is still fit for purpose.

### Reassessment of data gaps

Industry was unable to quantify (within the requested timeframe) what changes in dollar value/time could be attributed to using the proposed model. Industry feedback will be sought post implementation to determine if these values can be determined in practice

# 3. What policy options are you considering

The TGA is considering 3 options to be used in ingredient risk assessments. Each option demonstrates how to estimate daily sunscreen exposure (or “external exposure”) in Australia to calculate the SED. The SED was then used to calculate the maximum safe concentration using the MoS formula (see How risk for ingredients is evaluated).

These options are not intended to be included in legislation but will be provided as guidance for industry when making new ingredient applications.

Many secondary sunscreen products, such as cosmetic sunscreens, are not considered to be therapeutic goods and are therefore ‘excluded’ from therapeutic goods regulation. These cosmetic sunscreens fall under the regulation by the Australian Industrial Chemicals Introduction Scheme (AICIS), which oversees the introduction of ingredients in cosmetic sunscreens that comply with the Therapeutic Goods (Excluded Goods) Determination 2018. As these products are excluded from TGA regulation, the TGA has no authority to determine how the safety of the ingredients in these products are assessed. Therefore, the options apply to sunscreens regulated as therapeutic goods and not to those sunscreens excluded form therapeutic goods legislation. For more information, refer to Therapeutic sunscreens.

Therapeutic sunscreens must be included in the ARTG and are assigned an AUST L or AUST R number, noting currently, there are no registered sunscreens with an AUST R. Consumers can identify therapeutic sunscreens by the presence of the AUST L or AUST R number on the product label.

It is important to note that the proposed options are only related to sunscreen exposure assumptions used in the risk assessment process. However, any exposure assumptions are only one part of the risk assessment process, which depends on various other factors such as the available safety data. The risk assessment process and data requirements are standardised and the same for all options; they are not under consideration in the 3 options.

In relation to existing sunscreen ingredients, the options do not propose new regulatory requirements for currently approved sunscreen ingredients, such as reduced permitted concentrations stipulated in the Therapeutic Goods (Permissible Ingredients) Determination or the Poisons Standard. However, the TGA will use the consistent methodology provided by the adopted model to complete safety reviews of ingredients.

# Alternative options considered

## International approaches

In considering alternative options, the TGA researched methods being used internationally and determined that the SCCS model is the widely recognised international framework used in various regions.

Stakeholders were invited as part of the public consultation to provide any alternative international models, but none were identified. It appears that no other overseas jurisdiction has developed a similar model or methodology. Accordingly, the SCCC model has been proposed for adoption in Option 2.

In the USA, the FDA recommends Maximal Usage Trials (MUsT) to assess systemic exposure of a topical active ingredient, including sunscreen ingredients. Subjects are dosed at the highest daily dose and frequency proposed in the product labeling until levels of the active ingredient have reached steady state. The FDA uses information from a MUsT to identify the potential for systemic exposure and determine the need for additional safety data to support a finding that an active ingredient is generally recognized as safe and effective (GRASE) for its intended use. As the MuST is used on case-by-case basis for specific products and is not based on general consumer usage and exposure, it was not considered a viable option for adoption by the TGA to achieve the objectives of the proposed intervention.

## Domestic approaches

One possible alternative is to adopt the Cancer Council Australia's guidelines of reapplying sunscreen every 2 hours with 140 mL sunscreen application for a full-day full body sun exposure. However, industry feedback has been that this figure is far in excess of actual consumer sunscreen usage. It also does not account for the unique scenarios outlined in the ASEM calculations.

Another option is to allow industry to develop their own exposure model. However, the ability for the various stakeholders to agree on an approach may be challenging, time consuming and not achievable.

# Exposure Model (ASEM)

The Australian Sunscreen Exposure Model (ASEM) is proposed to accurately calculate sunscreen use that accounts for the diverse needs of Australians and integrates the expected sunscreen application practices that align with current Australian recommendations, rather than utilising international models that do not. This ensures that sunscreen ingredients are evaluated for safety based on how they are, and recommended to be, used in Australia today.

The objective of this approach is to affirm the safety of sunscreen ingredients, considering the highest plausible sunscreen use throughout the year, for the most sensitive population. To achieve this, 6 theoretical ASEM scenarios have been developed to represent a broad spectrum of regular sunscreen usage patterns across different demographics across Australia (see exposure model at Table 8). These scenarios provide the highest estimated average daily sunscreen exposure, to calculate maximum safe concentration of a sunscreen ingredient using the SED and MoS formulas.

The ASEM has been developed as a significant advancement for performing sunscreen exposure calculations that reflect the unique conditions and practices in Australia today. It aims to calculate safe levels of new ingredients proposed for use in Australian sunscreens, as well as reassess existing ingredients when new evidence suggests potential risks. Our goal is to ensure the approval of sunscreen ingredients is based on current information and scientific best practice so that sunscreens continue to be used safely and effectively by all Australians as one of the measures to prevent skin cancer.

## How the Australian Sunscreen Exposure Model (ASEM) works

The TGA draws upon the same risk assessment method developed by the SCCS for cosmetic ingredients to calculate the SED and MoS. However, the ASEM utilises a different estimated daily sunscreen exposure (external exposure) than is used by the SCCS to calculate the SED and MoS.

The SCCS estimated daily sunscreen exposure is expressed in 2 ways as shown in Table 4:

**Table 4: SCCS methods of expressing estimated daily sunscreen exposure**

| How dermal absorption data is reported | Estimated daily exposure | Estimated daily exposure per unit body weight* |
|---|---|---|
| Method 1 (%) | 18 g/day (i.e. 9 g of sunscreen applied twice daily) | 300 mg/kg bw/day |
| Method 2 (µg/cm$^2$) | 35,000 cm2/day (i.e. 2x whole body applications daily) | 583 cm2/kg bw/day |

*SCCS uses a default human body weight of 60 kg

The ASEM is a model to calculate the estimated average daily sunscreen exposure using a formula, and the input into that formula is based on Australian expected sunscreen use scenarios. For the purpose of regulatory risk assessments, the TGA has established the highest estimated average daily sunscreen exposure using the ASEM, that is proposed to be used to calculate SED and MoS, rather than the SCCS values above. The highest estimated average daily sunscreen exposure values are expressed below depending on how dermal absorption data for the ingredient is reported, as shown in table 5:

**Table 5: SCCS methods for determining dermal absorption**

| How dermal absorption data is reported | ASEM highest estimated average daily sunscreen exposure |
|---|---|
| Method 1 (%) | 673 mg/kg bw/day |
| Method 2 (µg/cm2) | 336 cm2/kg bw/day |

The following aspects of the ASEM that establish the above highest estimated average daily sunscreen exposure values are discussed below:

1. ASEM formula
2. ASEM scenarios
3. Calculations for establishing the highest estimated average daily sunscreen exposure

## ASEM Formula

The ASEM formula is a way to calculate and therefore estimate how much sunscreen is used daily. It is based on data for skin surface area, age, and body weight for the Australian population. The formula calculates the average daily sunscreen exposure by considering how many times it is applied a day, number of days of the year it is applied, and the skin surface area of each body part it is applied to.

$$ASEM\ (method\ 1) = \frac{Appl\ Rate \times SSA \times AF \times Duration}{Bw_t \times AT}$$

$$ASEM\ (method\ 2) = \frac{SSA \times AF \times Duration}{Bw_t \times AT}$$

where:

**Table 6: ASEM Parameters**

| Parameter | Description | Explanation |
|---|---|---|
| **ASEM** | Estimated daily sunscreen exposure (mg/kg bw/d) or ($cm^2$/kg bw/day) | The ASEM formula provides the amount of sunscreen applied to the skin per day relative to body weight (kg). The amount is expressed in units of either mass (mg) or surface area ($cm^2$), depending on how the data for dermal absorption of an ingredient is reported. |
| **Appl Rate** | Application rate of product mg/$cm^2$ | For a sunscreen product to reach the labelled sun protection factor (SPF), it must be applied in quantities similar to those used in SPF testing. This application rate of 2 mg/$cm^2$ is specified in the Sunscreen Standard.<br>**NOTE:** Appl rate is not required for Method 2 calculations because it is accounted for as part of the dermal absorption study protocol. |
| **SSA** | Surface area of skin sunscreen applied to ($cm^2$) per application | The skin surface area exposed to sunscreen (per application) is predicted based on the practices outlined in the ASEM scenarios (Table 8) for different population groups and activities e.g. an individual working outdoors may be wearing a hat, shorts. half-sleeved shirt and footwear, and therefore the exposed skin where sunscreen is applied would include the face, neck, hands, forearms, and lower legs. The scenarios account for parts of Australia with warmer climates where less clothing may be worn year-round.<br>The Australian Exposure Factor Guidance publication (enHealth) (DOHAC 2012) provides the most up-to-date information that can assist with assessing the human health risks from environmental hazards. It contains information on skin surface area (for different body parts) and body weight for adults and children. The data underlying this information is reliant on overseas data derived from either empirical data (actual measurements of skin areas) or algorithms that have extrapolated from weight and height measurements to generate skin (body) surface area values. The data utilised for the ASEM is based on enHealth (DOHAC 2012) data in:<br>• Table 3.2.3 and 3.2.5 for skin surface area of body parts for adults, adolescents and children<br>• Table 2.2.1 and E2 for body weights for adults (≥18 years), adolescents and children<br>enHealth reports both mean and 95$^{th}$ percentile value for SSA and BW (DOHAC 2012). The TGA has referred to the 95$^{th}$ percentile SSA and BW data for the ASEM calculations. |
| **Bwt** | Body weight linked to SSA (kg) | |
| **AF** | Application Frequency (applications/day) | Application frequency is expressed as the number of sunscreen applications per day. This can range from 2 – 3 applications per day for the different exposure scenarios outlined in ASEM Scenarios. |
| **Duration** | Annual Use (days) | Duration is expressed as the number of days in a year sunscreen application/exposure is expected to occur. The ASEM scenarios for the use of sunscreens in Australia provides information on the duration anticipated by different population groups. |

| Parameter | Description | Explanation |
|---|---|---|
| **AT** | Averaging time (365 days) | An average daily dose based on exposure over a 1-year period (i.e. 365) is being calculated. |

All the variables in the ASEM formula (SSA, BW, Age, AF and Duration) can change based on how the sunscreen is used and who it is used by. The respective input values for these variables are described in the ASEM scenarios below.

## ASEM Scenarios

It is clear that the use of a single maximum daily-use scenario, i.e. a full day at the beach with multiple reapplications of sunscreen (that would amount to ~140 mL application daily), is not useful for determining the safety of sunscreen ingredients for the Australian population as a whole. Hence 6 sunscreen use scenarios have been developed to account for the Australian context, the most current Australian research, and national guidelines and policies, with consideration given to:

1. The frequency of sunscreen application in both occupational and recreational contexts.
2. How sunscreen may be used by different age groups.
3. The environment (sun exposure) that an individual may be in.
4. Clothing that an individual is likely to be wearing in that environment.
5. The total skin surface area for exposed skin where sunscreen is likely to be used.
6. The number of days sunscreen is applied in a year, factoring in variables such as weather conditions, and different use based on weekday vs weekend activity.

Table 8 describes the 6 ASEM scenarios.

## How the ASEM scenarios estimate days sunscreen is applied in a year

The ASEM scenarios (Table 8) consider sunscreen exposure across weekdays and weekends to account for the highest-use case across a year, which is divided by 365 to give the average daily sunscreen exposure. The use of sunscreen is required when exposed to the sun year-round for parts of Australia where the UV index consistently exceeds 3, such as Darwin, Brisbane, and Perth etc. as discussed under 'Current evidence-based sunscreen use guidelines' above.

**Weekday exposure** is estimated based on a 5-day work week (i.e. 5 x 52 = 260 days annually), then adjusted for days of heavy rainfall (>10 mm). It is acknowledged that low rainfall days (rainfall ≥1 mm) with a UV index ≥3 may still necessitate sunscreen use (e.g. partly cloudy days, rainfall only for small period or in evening) as sun damage is also possible on cloudy days, since UVR can penetrate some clouds, and may even be more intense due to reflection off the clouds (Cancer Council Australia 2024c). Additionally, people are likely to be indoors on heavy rainfall days (rainfall ≥10 mm), thereby negating the use of sunscreens on such days. Average heavy rainfall days were calculated using BOM climate data (BOM 2024e) for rainfall for the past 3 years (2021-2023) for locations across Australia (see Table 7). The average weekly total heavy rainfall days was assumed to be 20 days (i.e. 5/7 x 29). Total weekdays of exposure were calculated as **240 days** (260 – 20). This has been used for the assumed highest-use plausible duration of sunscreen use on weekdays in scenarios 1 to 4.

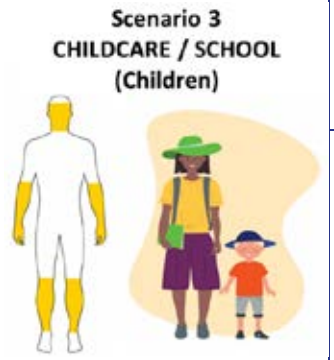
**Table 7: Average heavy rainfall days for Australia (2021-2023)**

| Location | | Rainfall ≥ 10mm days | | |
|---|---|---|---|---|
| **Station** | **City** | **2021** | **2022** | **2023** |
| 94029 | Hobart | 17 | 20 | 13 |
| 86232 | Melbourne | 23 | 21 | 13 |
| 23034 | Adelaide | 11 | 8 | 13 |
| 9021 | Perth | 27 | 26 | 18 |
| 14015 | Darwin | 50 | 58 | 43 |
| 40913 | Brisbane | 42 | 45 | 22 |
| 66006 | Sydney | 42 | 77 | 32 |
| 70351 | Canberra | 28 | 30 | 25 |
| **3-year average** | | **29** | | |

**Weekend exposure** is estimated for recreational activities that involve extended sun exposure, such as beach outings or outdoor activities such as water sports and fishing. This exposure is calculated for one day each weekend over a 6-month period from October to April, which is conducive to these activities due to warmer weather. The calculation does not deduct the average annual heavy rainfall days for weekends (2/7 x 29 days = 9 days) because the estimated exposure already accounts for only 25% of all weekend days annually, and 50% of all weekend days from October to April. It is assumed that the remaining 50-75% of weekend days would cover non-exposure days, including those with weather not suitable for prolonged outdoor activities. Therefore, the exposure duration for scenarios 5 and 6 is set at **26 days**, representing one day of sunscreen exposure for each of the 26 weekends in the 6-month warmer weather period

**Table 8: Six ASEM scenarios**

| Scenario<br>Yellow areas represent sunscreen applied to skin | | Parts of body applied | AF (applications/day) | Duration (days /year) | Description |
|---|---|---|---|---|---|
|  | Infrequent sun exposure. Limited sunscreen use.<br><br>Office Retail<br>Hospitality<br>Health worker<br>Vehicle operator | Head (including face and neck), hands | Up to 2 | 240 | This scenario accounts for daily sunscreen application practice for adults undertaking indoor work during the **weekdays**. This population is likely to wear formal or semi-formal clothing that fully covers the torso, arms, legs, and footwear. It presumes that sunscreen is applied once in the morning and once again during morning tea, lunch, or afternoon.<br>This is supported by the 'Current evidence-based sunscreen use guidelines' discussed above. Also see Whiteman et al. (2019). |
|  | Regular sun exposure. Limited sunscreen use.<br><br>Daily exercise<br>Dog walking<br>Gardening<br>Other recreation | Head (including face and neck), hands, ¾ arms, ¾ legs | Up to 2 | 240 | This scenario accounts for daily sunscreen application for adults (including active retirees) undertaking outdoor recreational activities during **weekdays**.<br>This population, particularly in warmer regions of Northern Australia, are likely to wear sport/casual clothing that may cover approximately ¼ of the arms and legs, torso and footwear. It presumes that sunscreen is applied once in the morning/start of the activity and once again halfway into the activity.<br>This is supported by the 'Current evidence-based sunscreen use guidelines' discussed above. Also see ASSC (2023) and Whiteman et al. (2019). |

| Scenario<br>Yellow areas represent sunscreen applied to skin | | Parts of body applied | AF (applications/day) | Duration (days /year) | Description |
|---|---|---|---|---|---|
|  | Frequent sun exposure. Regular sunscreen use.<br><br>Childcare (1-2 years old)<br>School children (under 18) | Face, neck, hands, ½ arms, ½ legs | Up to 3 (Childcare)<br>Up to 2 (School) | 240 | This scenario accounts for daily sunscreen application for children (above one year of age) attending sun smart childcare services (and schools) during the **weekdays**.<br>This population, particularly in warmer parts of Australia, are likely to wear hats and clothing that covers the torso, ½ arms and legs, and footwear. Sunscreen is applied frequently as a policy/practice in the majority of the early childhood centres but sun protection behaviours tend to reduce in older children and therefore sunscreen has been assumed to be applied up to two applications per day in older children.<br>This is supported by the evidence under the heading 'Sunscreen use in children' discussed above, in particular see Cancer Council SA (2018).<br>The estimation of sunscreen exposure for childcare settings is based on toddlers aged above 12 months instead of 6 to 12 months, as children normally learn to walk on their own between 12-15 months of age (DOHAC 2023; ACECQA 2024) and are more likely to be exposed to the sun (and consequently sunscreens) in a childcare setting relative to a 6-12-month-old child. Moreover, as discussed under the heading 'Sunscreen for infants (birth to 12 months)', infants under 12 months are not recommend to be exposed to the sun, and children under 6 months are not recommended to use sunscreen. |
|  | Frequent sun exposure. Regular sunscreen use.<br><br>Agricultural worker<br>Grounds keeper<br>Landscaper<br>Tradesperson<br>Surf lifeguard | Face, neck, hands, ½ arms, ½ legs | Up to 3 | 240 | This scenario accounts for daily sunscreen application practice for adults engaging in outdoor work (as their main occupation) during **weekdays**.<br>This population, particularly in warmer regions of Australia, are likely to wear specific workwear including a hat, clothing that fully covers the torso, ½ arms and legs, and footwear. Sunscreen is applied once in the morning, during lunch/midday and in the afternoon as this would include professions that are expected to spend long periods of time during the day (~6 hours) during peak UV periods.<br>This is supported by the evidence under 'Sunscreen use by outdoor workers' discussed above. |

| Scenario<br>Yellow areas represent sunscreen applied to skin | | Parts of body applied | AF (applications/day) | Duration (days/year) | Description |
|---|---|---|---|---|---|
|  | Prolonged sun exposure. Extensive sunscreen use. | Face, neck, hands, ½ legs, feet | Up to 3 | 26 | This scenario accounts for daily sunscreen application for sun-smart adults and children, undertaking outdoor recreational activities that lead to prolonged sun exposure on **weekends**.<br>This population is likely to wear hats and clothing such as a long sleeve shirt/rashie, shorts/boardies that cover ½ legs. Sunscreen is applied once in the morning/start of the activity and twice again during the day, particularly due to swimming, sweating or towel drying that may remove the product.<br>This is supported by the evidence under 'Sunscreen use by the general population' and 'Current evidence-based sunscreen use guidelines' discussed above. |
| | Full day in the sun (beach or other activities) | | | | |
|  | Prolonged sun exposure. Extensive sunscreen use. | Full body | Up to 3 | 26 | This scenario accounts for sunscreen application for adults and adolescents spending full day at the beach leading to prolonged sun exposure on **weekends**.<br>This population is likely to wear minimal swimwear. It presumes that sunscreen is applied once in the morning and twice again during the day, particularly due to swimming, sweating or towel drying that may remove the product.<br>This is supported by the 'Current evidence-based sunscreen use guidelines' discussed above for sunscreen application if the full body is exposed to the sun.<br>This scenario does not include children, as they are typically supervised by parents and expected to wear sun-smart attire, including hats and protective clothing, as outlined in scenario 5. |
| | Full day at the beach | | | | |

## Calculations to establish highest estimated average daily sunscreen exposure

The TGA has calculated the sunscreen exposure for each ASEM scenario and combined the weekday and weekend scenarios to provide a yearly realistic exposure. These yearly exposure scenarios are:

1. For adults: Scenarios 4 + 6.
2. For secondary school children: Scenarios 3 + 6.
3. For other children, including toddlers, pre-school, and primary school children: Scenarios 3 + 5.

To derive the estimated average daily sunscreen exposure, the output was divided by 365 days.

**Scenarios 3 and 5 for toddlers aged 1-2 years old provided the highest estimated average daily sunscreen exposure per kg/bw** due to:

- their high skin surface area to body weight ratio
- high estimated sunscreen exposure based on the scenarios

All the calculations for the estimated daily sunscreen exposure for each age group and scenario, and the combinations of the above scenarios (including how Australian skin surface area and body weight data have been used) were provided in the **ASEM Calculations Microsoft Excel file published on the TGA website as part of the consultation** (see tab '2. ASEM calculations'). The calculations for Scenario 3 and 5 for toddlers aged 1-2 years are provided below:

**Estimated daily sunscreen exposure for Method 1 (%)**

Scenario 3 = 607 mg/kg bw/day
Scenario 5 = 66 mg/kg bw/day

**Highest estimated average daily sunscreen exposure Method 1 (%)**

Scenario 3 + Scenario 5 = 607 + 66 = **673 mg/kg bw/day**

**Estimated daily sunscreen exposure for Method 2 (µg/cm2)**

Scenario 3 = 303 $cm^2$/kg bw/day
Scenario 5 = 33 $cm^2$/kg bw/day

**Highest estimated average daily sunscreen exposure for Method 2 (µg/cm2)**

Scenario 3 + Scenarios 5 = 303 + 33 = **336 $cm^2$/kg bw/day**

Because the ASEM formula calculates the highest estimated **sunscreen exposure as a proportion of kg body weight per day**, risk assessments using the SED and MoS calculations can be conducted using this value to account for any body weight (i.e. accounting for adults or children). This approach ensures that our risk assessment comprehensively cover the highest exposure for all Australians and ensure ingredients are safe to be used by everyone, no matter their age, weight, or outdoor activity.

# Option 2 – Scientific Committee on Consumer Safety (SCCS) sunscreen exposure model

This option considers formally adopting the SCCS sunscreen exposure model, as outlined in the SCCS guidance for testing cosmetic ingredients 12th revision (SCCS 2023). The SCCS is a Comparable Overseas Body that the TGA recognises and relies upon for abridged risk assessments.

This model is recognised in many international regions where sunscreens are regulated as cosmetics such as Europe and has been used in previous TGA assessments and submitted by sunscreen ingredient applicants.

This option is being considered for its international application in Europe. However, the TGA seeks to ensure that any model adopted is reflective of Australian sunscreen use and provides a realistic and safe framework for evaluating sunscreen ingredients.

Stakeholders were invited as part of the public consultation to provide their perspectives on the SCCS model's suitability for the Australian context, including any proposed modifications to the model that would make it a better alternative than the other options.

## How the SCCS sunscreen exposure model works

To determine the expected SED of a sunscreen ingredient in humans, exposure models generally consider the daily amount of sunscreen applied per kg body weight, in combination with the dermal absorption potential (in %) and concentration of the substance under consideration.

The SCCS uses two different estimated daily sunscreen exposure values to calculate SED, and, consequently, the MoS. Different sunscreen exposure values and methods are used depending on the way the data for dermal absorption of a sunscreen ingredient is reported:

### *Method 1*

If the dermal absorption is based on the percentage dermally absorbed (%), the SCCS recommends a default daily sunscreen usage of 18 g/day. The SCCS calculations of **18 g/day** are **not based on a 2 mg/cm² application thickness** required to achieve the claimed sunscreen SPF rating, but data about habits and practices derived from surveys and research from non-Australian countries.

### *Method 2*

If the dermal absorption is based on the absolute amount bioavailable (µg/cm²), the SCCS recommends the skin surface area (SSA) expected to be applied with sunscreen is **17,500 cm²** (1.75 m²) and frequency of application is **2 applications/day**. This is equivalent to SSA of 3.5 m²/day. This is shown in the SCCS equations for calculation of SED (SCCS 2023), as below:

### Method 1

$$SED = E_{product} \times \frac{C}{100} \times \frac{DA_p}{100}$$

Where:

| | |
|---|---|
| SED (mg/kg bw/d) | Systemic Exposure Dose |
| $E_{product}$ (mg/kg bw/day) | Estimated daily exposure to a sunscreen product per kg body weight, based upon the amount applied and the frequency of application (Note: for calculated relative daily exposure levels for sunscreen lotion, an amount of **18 g/day** is used by SCCS and default body weight used is **60 kg**). |
| C (%) | Concentration of the substance under study in the finished sunscreen product on the application site. |

| | |
|---|---|
| $DA_p$ (%) | Dermal Absorption expressed as a percentage of the test done assumed to be applied in real-life conditions. |

When dermal absorption potential is expressed in µg/cm$^2$ (not as a %) the estimated daily exposure to a sunscreen is evaluated based on the skin surface area sunscreen is applied to per kg body weight. This is then used in combination with the dermal absorption potential of the substance under consideration to determine the SED as shown in the calculation method 2 equation below.

### Method 2

$$SED = \frac{DA_a \times 10^{-3} \times SSA \times f_{appl}}{bw}$$

Where:

| | |
|---|---|
| SED (mg/kg bw/d) | Systemic Exposure Dose |
| $DA_a$ (µg/cm$^2$) | Dermal Absorption as an absolute amount absorbed (bioavailable) per surface area applied, resulting from an assay under in-use mimicking conditions. |
| SSA (cm$^2$) | Skin Surface Area expected to be treated with the finished product (According to Table 4 in SCCS Guidance, the default SSA value used by the SCCS for sunscreen lotion is **17,500 cm$^2$**). |
| $F_{appl}$ (day$^{-1}$) | Frequency of application of the finished product (According to Table 4 in SCCS Guidance, the default frequency for sunscreen lotion used by the SCCS is **2 applications per day**). |
| Bw (kg bw) | Human body weight (the default value used by SCCS is **60 kg**) |

The SCCS estimated daily sunscreen exposures are summarised in Table 9

**Table 9: SCCS methods of expressing estimated daily sunscreen exposure**

| How dermal absorption data is reported | Estimated daily sunscreen exposure | Estimated daily exposure per unit body weight* |
|---|---|---|
| Method 1 (%) | 18 g/day (i.e. 9 g of sunscreen applied twice daily) | 300 mg/kg bw/day |
| Method 2 (µg/cm$^2$) | 35,000 cm2/day (i.e. 2x whole body applications daily) | 583 cm2/kg bw/day |

* Estimated daily exposure per unit body weight is calculated by dividing estimated daily sunscreen exposure by the SCCS default human body weight of 60 kg.

The TGA notes that depending on the data available, these 2 methods result in substantial differences in the MoS calculation for the same ingredient. This means in some cases the SCCS calculations result in less or more conservative calculations for the MoS than the ASEM (Option 1).

## Background for the SCCS estimated daily sunscreen exposure values

For method 1, the SCCS model uses an estimated daily sunscreen exposure of 18 g per day, a figure derived from studies outside Australia, such as Biesterbos et al. 2013, in the Netherlands (SCCS 2021). This figure is further supported by research from Gomez-Berrada et al. (2017 and 2018) (encompassing 75 studies in adults and children across Mauritius, Spain, France and Italy (p. 98, SCCS 2023).

For method 2, the SCCS model assumes sunscreen is applied twice a day to the whole adult body.

The SCCS does not consider the recommended sunscreen application thickness (2 mg/cm$^2$) required to achieve the labelled SPF ratings for either of these two methods.

### How the SCCS model considers exposure in children

The default body weight used by the SCCS is 60 kg, and the SCCS sunscreen exposure model does not differentiate different age groups. However, the SCCS guidance acknowledges that the skin surface area to body weight ratio (SSA/BW) between children and adults are different (SCCS 2023). The ratio between the SSA/BW of children and adults changes from 0- to 10 years and is 2.3 at birth,1.8 at 6 months, 1.6 at 12 months, 1.5 at 5 years, and 1.3 at 10 years (Renwick 1998). The ratio between the SSA/BW children of 0 to 1 year of age and that of adults is at maximum 2.3. The SCCS considers that the inter-individual variation in SSA/BW is covered by the generally accepted default uncertainty factor value of 100 (10 for interspecies variations and 10 for intraspecies variations) for intact skin used in the MoS calculation. The SCCS also notes that for certain specific compounds the potential differences in metabolism between newborns/infants up to 6 months and adults could require extra consideration, however in general, the SCCS is of the opinion that there is no need for an additional uncertainty factor for children when intact skin is present (SCCNFP 2002).

However, the current SCCS model is based on European and other country usage patterns and does not account for Australian use patterns, or the amount of sunscreen application required to achieve the labelled SPF[23] rating. While the SCCS uses a 60 kg bodyweight estimate in their calculations, the TGA has historically used a more conservative bodyweight estimate of 50 kg in some assessments. Further, the SCCS method shows a substantial disparity in the risk assessment calculations depending on whether data for dermal absorption of an ingredient is reported in µg/cm² or as a percentage.

## Option 3 – Status Quo

Noting the TGA draws upon the same risk assessment method developed by the SCCS for cosmetic ingredients to calculate the SED and MoS, this option considers maintaining the *status quo*, where the standard estimated daily sunscreen exposure value for sunscreen ingredient risk assessments in Australia are not formalised.

Rather, risk assessment for sunscreen ingredients will be conducted on a case-by-case basis through a variety of risk-based methodologies that may utilise different estimates of daily sunscreen exposure.

This may mean that ingredient risk assessments may be based on estimated sunscreen exposure values such as those used in either Option 1, Option 2, or other approaches based on case-by-case justifications.

# 4. What is the likely net benefit of each option?

## Consideration of regulatory cost

The proposed options are only related to sunscreen exposure assumptions used in the risk assessment process (how to estimate daily sunscreen exposure or “external exposure”). These assumptions serve as a means for the TGA to undertake risk assessments to determine the safe concentration limits for sunscreen ingredients (see How risk for ingredients is evaluated). However, the risk assessment process and safety data requirements, are the same for all options. Further, for

[23] The SPF is the level of protection a sunscreen offers against sunburn. It relates to the amount of time it takes for redness to appear on the skin compared to when no sunscreen is applied.

ingredients that neither absorb through the skin nor pose a risk of systemic exposure, an exposure model is not necessary since there is no need to account for systemic exposure.

Risk assessments are typically undertaken for new ingredient applications, but in some cases, can also be undertaken for currently approved ingredients where there are public safety concerns. In the latter case, these risk assessments are highly dependent on the data (including the quality of data) available at the time of the assessment, and the circumstances, including if there are existing products affected and if they require reformulation and/or label changes. Similarly, in response to the public consultation, Consumer Healthcare Products Australia (CHP Australia) advised that they would be able to provide more information on the impacts and transition requirements once the TGA's safety review on sunscreen ingredients commences and they had greater clarity of the likely impact.

The options also do not propose new regulatory requirements or change the requirements for currently approved sunscreen ingredients, such as reduced permitted concentrations stipulated in the Therapeutic Goods (Permissible Ingredients) Determination or the Poisons Standard, or any labelling changes. As such, it is not possible to generate costings for comparison of future regulatory impacts of risk assessment outcomes that have not been undertaken and are circumstantial. These regulatory impacts are considered in separate processes under existing mechanisms (for example under amendments to the Poisons Standard or Therapeutic Goods [Permissible Ingredients] Determination).

The adoption of a consistent model is anticipated to have a uniform impact across all groups, without any significant differential effects or redistributive objectives. Rather the implementation of the model is expected to ensure that no stakeholder group is disproportionately affected. The adoption of a model will not restrict competition—consistent with question 1, Figure 1 of the Office of Impact Analysis' guidance on Competition and Regulation[24]—as such consumers are not likely to be worse off. Instead, the proposal provides a consistent platform for stakeholders, and it is in the public interest due to potential concerns with sunscreen active ingredients that can be absorbed into the body and the need to ensure they are consistently regulated to be safe. Further, there is potential for efficiency and innovation when there is increased clarity about the assessment requirements, which could lead to enhanced productivity and types of products that are available.

In relation to new ingredient applications, the TGA contacted both peak industry bodies representing sunscreen sponsors, suppliers and manufacturers, Accord and CHP Australia, for data to estimate the quantitative costs for each option. Data was requested to compare costs required to produce a dossier and work through the application process for a new ingredient that absorbs through the skin or where absorption cannot be excluded, using each option. For similar reasons to the above, both Accord and CHP Australia were not able to provide data that could be used to estimate costs as applications are highly circumstantial.

In the absence of data to indicate how adopting a model would influence the provision of new ingredient applications, it is not possible to ascertain quantitative negative or disproportionate impacts.

As the options proposed relate to ingredients, not products, the impact on proposed new sunscreen products including a new approved ingredient may be that their formulation will have to be adjusted to meet the safe level of active ingredient as determined by the accepted model. However, it is assumed that a new product formulation will only be developed after an ingredient has been assessed and approved, so no additional costs should be involved for this process.

The impact for imported products cannot be estimated until it is known what ingredients are included in the formulation. It is possible that Australian restrictions on individual ingredients may be more than or less than those permitted in overseas jurisdictions. Some industry respondents raised concerns that Australian-specific assessments could create trade barriers for European products. Different allowable concentrations in various countries may impact the supply of certain ingredients. These respondents emphasised the need to ensure a sufficient range of sunscreen active ingredients are available to formulate very high SPF products without compromising safety.

In industry consultation, the TGA has emphasised the differences between Australian environmental

[24] https://oia.pmc.gov.au/sites/default/files/2023-08/competition-and-regulation.pdf

and cultural conditions and the regulatory framework for sunscreens compared to Europe, which highlights the importance of having an assessment process tailored to Australia's needs.

Given that Australia has the highest incidence of skin cancer in the world, sunscreens designed primarily for UV protection are regulated as therapeutic goods with different compliance standards, unlike some sunscreens overseas that may be regulated as cosmetics. These differences can affect conclusions about the safety of ingredients, including approval of higher permitted concentrations in Australia compared to other countries. In contrast, alignment of international assessments may sometimes result in reduced availability of safe sunscreen ingredients in Australia. To ensure safe sunscreen active ingredients are not restricted from being used in Australian products, the TGA makes regulatory decisions following a careful analysis of the latest scientific evidence, tailored to Australia's distinct environmental conditions, health requirements, and regulatory framework.

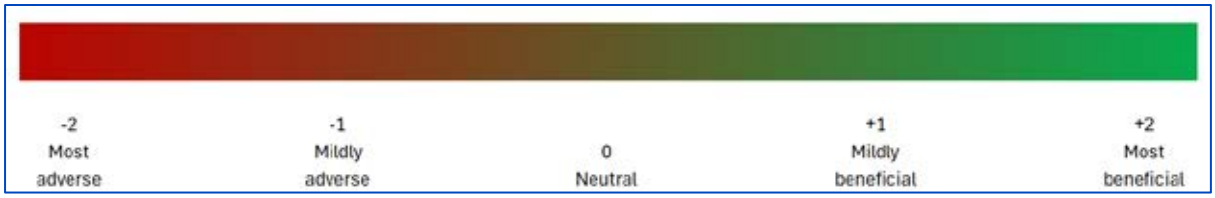
On account of the above, a quantitative estimate of regulatory burden is not feasible. As such, the most feasible way to compare the 3 options is to consider the qualitative reasons for and against each option. These qualitative costs for each option are discussed below.

## Net benefit based on qualitative analysis

Quantifying the benefits of each option is not feasible, as previously discussed (see Consideration of regulatory costs). Consequently, a multi-criteria qualitative analysis was performed for each option, using a score rating system for each potential cohort that may be affected (refer to Table 10). This approach helps to reflect the greatest benefit. Given the challenges in determining precise quantitative values, a scale from +2 to -2, (with 0 indicating no net change in benefit) was used to illustrate and compare the relative benefits of each option.

Each potentially affected cohort was assigned a score rating to account for the net benefit in the absence of quantitative data. The cohorts align with the three main objectives: ensuring the safety of sunscreens, enhancing consumer safety and trust in sunscreens and increasing regulatory certainty for the sunscreen industry. For a detailed qualitative analysis, refer to Comparison of the qualitative regulatory costs for each option.

**Impact rating scale**:




The analysis focuses on the impacts of each option on the following cohorts who *may* be most affected:

- Industry (including applicants/sponsors)
- Exporters
- Importers
- Australian consumers
- Government

**Table 10: Impacts of each option on specified cohorts**

| Cohort | Impact(s) | Score |
|---|---|---|
| **Industry (including applicants/sponsors)** | **Option 1 (ASEM):**<br>• Simple calculation to determine sunscreen exposure which produces consistent outcomes.<br>• Reduced discrepancies in risk assessments, due to there being a consistent approach and regulatory certainty as to the TGA's approach.<br>• Less likely to be contested, saving time and resources.<br>• Reduction in time taken to conduct evaluations due to the provision of consistent data and calculations.<br>• Reduced request for further information and/or liaising with applicants in search of information to assist with individual risk assessments reduces resources required by applicants.<br>• May not align with international jurisdictions that use the SCCS estimation of sunscreen use for risk assessments. This could lead to discrepancies where certain sunscreen ingredients are permitted overseas but restricted or limited to lower or higher maximum concentrations in therapeutic sunscreens in Australia. However alternatively, some ingredients could be permitted in Australia, or have higher maximum concentrations, than overseas.<br>• Consistency of regulatory outcomes can better support innovation and development of sunscreen ingredients. | +2 |
| | **Option 2 (SCCC model):**<br>• Limitation that there are variances in the calculated MoS depending on the method used, which may result in inconsistent evaluation outcomes.<br>• Provides less regulatory certainty than Option 1 due to potential for inconsistent evaluation outcomes.<br>• Reduction in time taken to conduct evaluations due to the provision of consistent data and calculations.<br>• Less time taken to request further information and/or liaising with applicants in search of information to assist with the risk assessment.<br>• Aligns with international jurisdictions that use the SCCS estimation of sunscreen use for risk assessments. Consistency of approach supports innovators of new ingredients by allowing them to provide data that meets the requirements of different agencies. While the data requirements are the same with the SCCS, the regulatory framework, and approval process is still different irrespective of what model was used. Alignment of the exposure calculations does not guarantee that the ingredient requirements would be suitable or the same in Australia under the legislative framework.<br>• Recognised by European nations and other international regions where sunscreens are regulated as cosmetic products. | +1 |

| Cohort | Impact(s) | Score |
|---|---|---|
| | **Option 3 (Status quo):**<br>• Allows greater flexibility to employ diverse scientific justifications to support evaluation of new sunscreen active ingredients.<br>• Subject to regulatory inconsistencies and discrepancies in risk assessments, i.e. overly conservative vs. less conservative.<br>• Evaluations are more prone to be challenged, increasing time and resources debating application decisions.<br>• Requires scientifically robust justifications, increased time for researching and drafting dossiers that may not be supported by a TGA evaluator.<br>• Resources used to seek further information and constant liaising with applicants. | -2 |
| **Domestic exporters** | All therapeutic sunscreens must be included in the ARTG to be exported from Australia. In addition, they must meet the regulatory requirements of the country they are importing to. The exposure models do not affect products in and of themselves but affect the approval of the ingredients and their restrictions, that would be included in products that could potentially be exported from Australia in the future. | |
| | **Option 1 (ASEM):**<br>• May not align with international jurisdictions, such as the EU that use the SCCS estimation of sunscreen use for risk assessments for their ingredients. This may mean products may have ingredients with different concentration limits (lower or higher) or restrictions in Australia vs internationally.<br>• Given the safety assessment for their ingredients is based on Australian conditions and they are also regulated as therapeutic goods in Australia, the reputation of Australian sunscreens may be enhanced, and increase demand in other countries with similar environmental conditions or consumers seeking higher standards. | +1 |
| | **Option 2 (SCCC):**<br>• Aligns with international jurisdictions such as European nations. However, alignment of the exposure calculations does not guarantee that the ingredient requirements would be the same in Australia under the legislative framework, or Australia's assessment using the SCCS model noting it can result in significant differences in the MoS using the same data. However, knowing that the ingredients were assessed using a European model may support their suitability for an export market where ingredients are approved based on SCCS evaluations. | +1 |
| | **Option 3 (Status quo):**<br>• No impact. | 0 |
| **Importers** | All therapeutic sunscreens must be included in the ARTG by a sponsor (impacts for sponsors discussed above) to be imported to Australia and must meet Australian regulatory requirements. The exposure models do not affect existing products in and of themselves or their ability to be imported but affect the approval of new ingredients that are not yet | |

| Cohort | Impact(s) | Score |
|---|---|---|
| | approved in Australia and their restrictions that could be included in future products supplied in Australia. | |
| | **Option 1 (ASEM):**<br>• May not align with international jurisdictions that use the SCCS estimation of sunscreen use for risk assessments. This could lead to discrepancies where certain sunscreen ingredients are permitted overseas but restricted or limited to lower maximum concentrations in therapeutic sunscreens in Australia. However alternatively, because SCCS assessments may result in significant differences in the MoS for the same data, some ingredients could be permitted in Australia, or have higher maximum concentrations, than overseas. This may mean the approval of future ingredients for use in Australian products result in some products are permitted to be imported whereas others could not. | -1 |
| | **Option 2 (SCCC):**<br>• Aligns with assessment of ingredients in international jurisdictions such as European nations. However, alignment of the exposure calculations does not guarantee that the ingredient requirements would be the same in Australia under the legislative framework where they are regulated as therapeutic goods, not cosmetics. Further, the SCCS model can result in significant differences in the MoS calculations using the same data. This means, irrespective of adopting the SCCS model, the approval of future ingredients for use in Australian products may mean some products could be imported whereas others could not. | +1 |
| | **Option 3 (Status quo):**<br>• No impact. | 0 |
| **Australian consumers** | **Option 1 (ASEM):**<br>• Specifically developed for Australia's unique environment, giving consumers confidence in the safety of sunscreens.<br>• Developed to account for the skin surface area, body weight representative of the Australian population across all age groups, ensuring safety in children and adults.<br>• Employed based on realistic highest use Australian scenarios to model the diversity of regular use by adults and children.<br>• The adoption of the model is not proposing changes to existing sunscreens, so no impact on sunscreen cost and availability.<br>• Anticipated to have a uniform impact across all groups, without any significant differential effects or redistributive objectives. | +2 |
| | **Option 2 (SCC):**<br>• 18 g per day exposure value is based on studies conducted outside of Australia, and not accounting to Australia's unique climate and skin cancer incidence. | -1 |

| Cohort | Impact(s) | Score |
|---|---|---|
| | • Australia has the higher UVR levels and highest incidence of skin cancer worldwide. Continued use of a non-Australian model may undermine confidence in sunscreen regulation.<br>• The adoption of the model is not proposing changes to existing sunscreens, so no impact on sunscreen cost and availability.<br>• Anticipated to have a uniform impact across all groups, without any significant differential effects or redistributive objectives. | |
| | **Option 3 (Status quo):**<br>• Differing approaches may not reflect the unique Australian context.<br>• Discrepancies in risk assessments may undermine consumer confidence.<br>• Option 3 is not proposing changes to existing sunscreens, so no impact on sunscreen cost and availability.<br>• Anticipated to have a uniform impact across all groups, without any significant differential effects or redistributive objectives. | -1 |
| **Government** | **Option 1 (ASEM):**<br>• Increased consumer confidence in the regulation of sunscreens in Australia.<br>• Increased use of sunscreens will lead to better health outcomes.<br>• Simple calculation for evaluators to determine sunscreen exposure which produces consistent outcomes.<br>• Reduced discrepancies in risk assessments, due to there being a consistent approach and regulatory certainty as to the TGA's approach. Supports consistent decision making.<br>• Less likely to be contested, saving time and resources.<br>• Reduction in time taken to conduct evaluations due to the provision of consistent data and calculations.<br>• Reduced request for further information and/or liaising with applicants in search of information to assist with individual risk assessments. | +2 |
| | **Option 2 (SCCC):**<br>• Potentially decreased consumer confidence in the regulation of sunscreen in Australia as the unique Australian environment not taken into consideration.<br>• Potential decreased use of sunscreens leading to negative health outcomes.<br>• Aligning with international approaches may enhance international reputation.<br>• SCCS model leads to significant discrepancies for the MoS calculation using the same data, which reduces consistency of | 0 |

| Cohort | Impact(s) | Score |
|---|---|---|
| | decision making, potential contestation, and requires further justification for which approach is used. | |
| | **Option 3 (Status quo):**<br>• Potentially decreased confidence in the regulation of sunscreen in Australia as the unique Australian environment not taken into consideration.<br>• Potential decreased use of sunscreens leading to negative health outcomes.<br>• Decisions may be challenged or contested, and require justification for approvals that use other approaches. | -1 |

Note: the proposed adoption of the ASEM does not affect existing products. Instead, it is used in the risk assessments for new sunscreen ingredients, and not existing ingredients unless there are safety concerns that arise that require a re-assessment of that ingredient. This approach is taken for any ingredient used in listed medicines, not just to those used in sunscreens.

The scores for each option are provided in Table 11. While there is an element of subjectivity to the analysis, Option 1 provides the highest level of positive impact to the subject cohorts.

**Table 11: Impact score for proposed options**

| Option | Score |
|---|---|
| Option 1 | **6** |
| Option 2 | **2** |
| Option 3 | **-4** |

# Impact on importers and exporters of sunscreens

## Importers

Sunscreens are regulated differently across international jurisdictions. In Australia, Canada and the United States of America, they are regulated as therapeutic goods, whereas in Europe they are regulated as cosmetic goods.

Each country has its own regulatory requirements and framework for import, export, supply and manufacturing. Furthermore, even if a model used internationally, such as the SCCS exposure model, were adopted in Australia, the approval of an ingredient that can be absorbed into the body (which is based on the MoS calculation) still significantly varies based on how the SCCS model is used even if using the same data. As such, this discrepancy leads to misalignment in international regulations and approvals of sunscreen ingredients with the same restrictions, irrespective of which exposure model is adopted.

For products that are imported into Australia, there are specific requirements: products must have specific Australian labelling requirements, be manufactured in accordance with the principles of Good Manufacturing Practice (GMP) from a facility approved by the TGA, and only include ingredients on the Therapeutic Goods (Permissible Ingredients) Determination. Imported products are also required to have Australian-specific stability testing, due to the higher humidity levels. Additionally, sunscreens must meet the standards set by the Australian/New Zealand Sunscreen Standard (AS/NZS) 2604 Sunscreen products – Evaluation and classification, requiring specific testing to comply with the SPF, water resistance and broad-spectrum claims. These requirements apply regardless of ingredient exposure model used.

### Exporters

The TGA does not record information about the proportion of products that are exported. To obtain this information, we would need to contact each sponsor individually, and there is no guarantee that sponsors would disclose this information. While a search of the ARTG can provide the total number of products, the number of these that are exported is unknown. Noting sunscreens are regulated differently internationally and the misalignment of international regulations discussed above which each country having its own framework for import, exposure, supply and manufacturing, exporters will always need to meet the requirements of the importing country which are unlikely to be the same as Australia's, irrespective of which exposure model is adopted.

### Hypothetical examples

An ingredient that is known to absorb through the skin is approved in Europe at a certain concentration (based on the SCCS model). If this ingredient is proposed for use in Australia, the ASEM can result in either a more conservative or a less conservative concentration compared to the European number. This is because the SCCS exposure model can result in approximately a 5-fold difference in the MoS number generated, based on the analysis method used in the calculations (i.e. Method 1 vs Method 2), even if using the same data. While the ASEM lends itself to generate only one number, as discussed in detail in Attachments 3 and 4 in the public consultation paper. Due to this discrepancy, estimated costs cannot be practically estimated. This was not contested during the ASEM consultation which included responses from European stakeholders.

The table below (Table 12) highlights the potential impact on importers and exporters due to a difference in the approved concentration scenarios.

**Table 12: Comparison of potential impacts on importers and exporters of sunscreens**

| Comparison of ingredient requirements between Europe and Australia | Impact on Australian importers | Impact on Australian exporters to Europe |
|---|---|---|
| Approved maximum ingredient concentration in Europe (based on SCCS model) is lower than in Australia. | No effect, if all other ingredient requirements are the same, and exporters also meet the Australian regulatory requirements. | May not be able to export products with ingredients above the European threshold. Noting that exporters must also meet the regulatory requirements of the importing country in Europe where they are regulated as cosmetics and may not contain certain ingredients in the cosmetic annexes (which do not apply in Australia). |
| Approved maximum ingredient concentration in Europe (based on SCCS model) is higher than in Australia. | May not be able to import products with ingredients above the Australian threshold. Noting that exporters must also meet the Australian regulatory requirements where sunscreens are regulated as therapeutic goods not cosmetics in Europe. | No effect, if all other ingredient requirements are the same, and the exporters also meet the regulatory requirements of the importing country in Europe. |

## Comparison of qualitative regulatory costs for each option

In theory, having a clear regulatory process, that provides certainty and consistency of assessments, enables applicants to develop dossiers and propose limits that will be treated consistently in the TGA assessment process. When not factoring in circumstantial aspects such as the quality of the dossier

or the actual safety data, the costs are theoretically decreased with increasing certainty and consistency of regulatory assessments.

Under Option 3 (status quo) there is no guidance on calculating the appropriate SED and the applicant would need to provide their own justification and calculations. While Option 3 offers applicants with greater flexibility to use diverse scientific justifications/rationales, there are inherent costs as applicants must furnish robust and substantial justifications. These may necessitate extra research and time investment, each incurring associated costs, to bolster their applications. As the costs for Option 3 are dependent on the quality and merit of an applicant's justification and time to assess that justification, they cannot be reliably calculated. Similarly, for Option 3, Accord noted that there is no transparency on the requirements and therefore the cost and effort cannot be estimated.

Option 1 and 2 offer a standardised, consistent exposure assumption process in guidance that require the applicant to read the guidance and input the existing data into a simple formula to calculate the SED. The SED is then used to calculate the MoS.

Option 1 offers the greatest consistency and certainty, Option 2 less, and Option 3 the least. This is because:

- Option 1 calculations for both methods 1 and 2 result in very similar, if not the same, MoS calculations based on the same safety data
- Option 2 can result in approximately a 5-fold difference between method 1 and 2 calculations
- Option 3 is uncertain and can vary case by case.

A comparison of risk assessments using Option 1 and 2 and the real world evidence demonstrating the benefits of Option 1 compared to Option 2 were discussed in detail in Attachments 3 and 4 in the public consultation paper.

# Option 1 – Australian Sunscreen Exposure Model (ASEM)

## Reasons for Option 1

- A standardised method for evaluating sunscreen ingredients reduces discrepancies in risk assessments. This uniform approach guarantees that ingredients are approved based on the same criteria, reducing and overcoming varied outcomes due to different types of data presented, such as those limitations observed with the SCCS method 1 and method 2 calculations. It levels the playing field for new ingredient applicants, providing regulatory consistency and certainty for ingredient evaluations, which facilitates the development and introduction of novel ingredients to the Australian market.
- Evaluations are less likely to be contested, saving time and resources for all stakeholders involved in application decisions. This streamlined process reduces potential delays in introducing new sunscreen ingredients and alleviates the regulatory burden of the processes due to unnecessary contention.
- The ASEM offers a simpler calculation to determine sunscreen exposure for regulatory purposes. This reduces the complexity of application dossiers that would simply be able to provide the absorption data and simple calculation, rather than discussing suitability in the Australian context or account for different age groups.
- The ASEM has been specifically developed for the Australian context, which has the highest incidence of skin cancer globally and a culture that enjoys outdoor activities. Consequently, Australians are advised to use sunscreen and other sun protection measures more diligently and regularly than in other countries with different circumstances. Moreover, the assessment of all therapeutic goods, including sunscreens, should be based on the amount they are used according to their directions to be effective. Therefore, the ASEM provides a model that accounts for these factors and ensures safety when used correctly. This approach bolsters confidence in

sunscreen regulation and allows Australians to trust in using sunscreen as a daily UVR protective measure for the entire family.

- The ASEM is grounded in current Australian evidence-based sunscreen use guidelines and research. It models sunscreen exposure based on how sunscreens are directed to be used to achieve effective UV protection. The ASEM models exposure of a sunscreen application thickness of 2 mg/cm2 to attain the labelled SPF, and while this thickness may not be commonly applied by many Australians, it is supported by studies indicating that some participants do apply sunscreen at the correct thickness or even more. This is particularly significant for therapeutic sunscreens in Australia, which are allowed to claim they may assist in preventing some skin cancers, a claim not permitted for sunscreens in Europe where they are considered cosmetics. Use of the ASEM ensures that sunscreens are safe for use according to their instructions, supporting the claims of effectiveness and promoting regular, liberal application as a preventative measure against skin cancer.
- The ASEM's reliance on current Australian guidelines means the model takes into account future expected sunscreen use, aligning with efforts from government and non-government organisations to promote the correct application of sunscreen to prevent skin cancer.
- Unlike the SCCS model, which uses for example, a single maximum daily use scenario (18 g/day) based on research from countries that are likely to have a very different context for sunscreen use than Australia, or a maximum full day at the beach daily use scenario (that would amount to ~140 mL application daily), the ASEM employs realistic highest-use Australian scenarios to model the diversity of regular daily use for adults and children. The ASEM caters to the safety of all Australians, especially frequent sunscreen users, while avoiding unnecessarily restricting effective sunscreen ingredients from the Australian market and guaranteeing assessments are fit for purpose.
- Recognising that systemic exposure to a sunscreen ingredient depends on the amount of skin it covers, and that individuals experience varying levels of exposure based on body weight, the ASEM employs skin surface area and body weights representative of the Australian population across all age groups. It places particular emphasis on safeguarding young children, who have the highest skin surface area relative to body weight, thereby affirming the safety of sunscreen use for the entire family in daily life, whether it be for work, school, or leisure activities.

## Reasons against Option 1

- This approach provides estimations of sunscreen use based on Australian evidence-based recommendations and limited research. However, it is important to note that actual comprehensive Australian sunscreen use data, combined with these recommendations, would provide a more robust model for estimating highest-use exposure in the Australian context. While gathering such extensive data that would be statistically representative of all Australians poses challenges, the ASEM scenarios and variables are derived from the best available information to date.
- The formal adoption of ASEM would not align with international jurisdictions that use the SCCS estimation of sunscreen use for risk assessments. This could lead to discrepancies where certain sunscreen ingredients are permitted overseas but restricted or limited to lower or higher maximum concentrations in therapeutic sunscreens in Australia. While the TGA recognises the SCCS as a Comparable Overseas Body (COB) where evaluation reports can be used for abridged evaluations, the Guidance on using evaluation reports from COBs clarifies that that use of a product or substance in the Australian context may differ from international use. The guidance further clarifies that the TGA retains the final regulatory decision to ensure safety, quality, and efficacy in accordance with the Australian regulatory framework.

# Option 2 – SCCS sunscreen exposure model

## Reasons for Option 2

- The SCCS model is recognised by European nations and other international regions where sunscreens are regulated as cosmetic products. Adopting the SCCS model would align regulatory risk assessments of sunscreen ingredients with these international jurisdictions.
- The SCCS model has been employed in previous TGA assessments and the current Application requirements for new substances in listed medicines (ARNS) guidance recommends using appropriate dermal exposure models from the SCCS's 11th revision guidance to calculate the maximum daily exposure for dermally applied ingredients.
- The SCCS is recognised by the TGA as a Comparable Overseas Body (COB) where evaluation reports can be used for abridged evaluations. However the Guidance on using evaluation reports from COBs clarifies that that use of a product or substance in the Australian context may differ from international use and the TGA retains the final regulatory decision to ensure safety, quality, and efficacy in accordance with the Australian regulatory framework.
- Evaluations may be less prone to being challenged/contested, reducing time and resources expended by all stakeholders in debating application decisions that are not based on a consistent methodology. This reduces potential delay of the introduction of new sunscreen ingredients but and reduces burden on the regulatory process from unnecessary contention.

## Reasons against Option 2

- One of the estimated daily sunscreen exposure values used by the SCCS is 18 g per day, a figure derived from studies outside Australia. Some of the supporting data for example, appears to be predominantly from Mauritius (57 studies), which, like other countries in Europe, has significantly lower skin cancer incidence rates compared to Australia. For example, in 2022, Mauritius had a melanoma and non-melanoma skin cancer age-standard incidence rate per 100,000[25] for both sexes of 0.24 and 4.2 respectively, compared with Australia which was 37 and 140.1, the highest rates out of all countries (IARC 2024b). Given Australia's high skin cancer rates and a culture that emphasises outdoor activities, the suitability of the 18 g per day exposure calculation is uncertain as Australians are encouraged to apply sunscreen more frequently, thoroughly, and diligently, as part of a broader sun protection strategy, which includes policies implemented in settings like childcare. The Australia context is likely to be very different from other countries with a lower incidence of skin cancer.
- The SCCS sunscreen exposure value of 18 grams per day is used for risk assessments but is not intended as a consumer usage recommendation (p. 98, SCCS 2023). The European Commission acknowledges that to achieve the claimed SPF protection level, sunscreen must be applied at the same density used in testing, approximately 2 mg/cm², equating to around 36 grams for an average adult's full body (European Commission 2006). Furthermore, the European Commission recommends that sunscreen products should include instructions to ensure adequate application for effective protection, along with a warning about the risks of insufficient application, such as 'Warning: reducing this quantity will significantly lower the level of protection' (European Commission 2006). While it is likely that many Australians may not apply sunscreen at the recommended thickness of 2mg/cm², it is reasonable to assume there are individuals who would achieve the intended SPF rating, and this application rate is also shown in the limited Australian research discussed above. The assessment of therapeutic goods, including sunscreens, must be based on how much is applied to be effective as per the directions provided. However, the applicability of the SCCS model for Australians who correctly use sunscreen, or its alignment with initiatives promoting correct sunscreen application in Australia, remains to unclear.

[25] The age-standardised rate is a summary measure of the rate that would have been observed if the population had a standard age structure, as age has a strong influence on cancer risk. The World Standard Population is used to calculate the incidence rate per 100,000 person-years (IARC 2024a)

- While the SCCS method is established, it has limitations that may lead to inconsistencies in risk assessments. Depending on the available data, the SCCS exposure calculation method can yield considerable differences in the MoS calculation for the same ingredient. This discrepancy could result in the same ingredient being approved under one set of data but rejected if presented in a different way. Such inconsistencies raise concerns about the appropriate calculation method for regulatory approvals and the potential for regulatory uncertainty if absorption data is presented in both % and ug/cm$^2$ requiring expert judgement for which calculation method will be most suitable.
- In Australia, therapeutic sunscreens are permitted to claim to 'assist in preventing some skin cancers' and 'reduce the risk of some skin cancers,' which is not permitted for cosmetic sunscreens in Europe. The efficacy of therapeutic goods, including sunscreens, should be evaluated based on the recommended usage to achieve their stated indications, a factor not considered in the SCCS model.
- While the ARNS refers to the SCCS 11$^{th}$ revision for calculating the maximum daily exposure of dermal substances, and the SCCS is included in the list of COBs, clarity is still needed on expectations for ingredient evaluations, particularly concerning the suitability of the SCCS model for the Australian context considering current Australian evidence-based sunscreen use guidelines and research discussed above for all populations, including children.
- Australia experiences higher UVR levels than any country in the European Union (WHO 2013) and has the highest incidence of skin cancer worldwide. Given the Australian outdoor lifestyle, it is reasonable to assume that Australians use, or should at least use, more sunscreen than other nations. Sunscreen in Australia play a vital role in public health and are permitted to make claims relating to preventing skin cancer and are regulated as therapeutic goods under stricter standards than in some international jurisdictions where they are classified as cosmetics. Continued reliance on a European exposure model, rather than developing a tailored Australian approach based on current evidence, could undermine confidence in sunscreen regulation and its use as a protective measure against UVR in Australia.

# Option 3 – Status Quo

## Reasons for Option 3

- Applicants have greater flexibility to employ diverse scientific justifications to support evaluations of new sunscreen ingredients. This may better account for technological advancements, changes in public behaviour, and emerging scientific evidence and sunscreen use guidelines and risk assessments.

## Reasons against Option 3

- The current approach has resulted in regulatory inconsistencies, leading to confusion and uncertainty. This is problematic given the lengthy research and development process required to bring new ingredients to market, with tests that may need to be conducted at the proposed concentration for final products. Uncertainty about the concentration that may be approved by the TGA, based on the assessment methodology, can stifle innovation and the development of new sunscreen ingredients.
- The absence of an agreed estimated daily sunscreen exposure value means there is no standardised method for evaluating sunscreen ingredients, potentially leading to discrepancies in risk assessments where some may be overly conservative, while others may not be conservative enough.
- Without a universally accepted approach, evaluations are more prone to being challenged, leading to increased time and resources expended by all stakeholders in debating application decisions. This not only delays the introduction of new sunscreen ingredients but also burdens the regulatory process with unnecessary contention.

- Applicants may be required to provide scientifically robust arguments to support their chosen approach, which may not be supported by the TGA evaluator if not well-founded. Given the complexity of assessing sunscreen exposure, this could pose significant challenges and add unnecessary regulatory costs for new ingredient applicants.
- Some estimated daily sunscreen exposure values proposed by applicants, and those ultimately employed may not adequately reflect the unique Australian context, such as the higher levels of UV exposure and adherence to current evidence-based guidelines for effective sun protection. The methods employed may not account for Australian practices today for the most frequent sunscreen users.

# Consideration of regulatory cost

A meaningful or comprehensive regulatory burden estimate cannot be calculated due the absence of data, the large number of associated uncertainties and circumstantial aspects. Information to quantify the impacts were also not able to be provided by the industry.

As such, for the purposes of the IA, a purely hypothetical, worst-case example is provided below to demonstrate what the potential regulatory burden for applicants may be for having regulatory certainty about the exposure calculation that would be used (Option 1), and that would result in approval of the ingredient at the first application attempt. The cost of preparing an application using each option is considered, on the basis that the data (e.g. the toxicity and skin absorption studies) would be the same in each application, and only the exposure calculation and or accompanying justification differs for each option considered.

Option 1 is the only choice that guarantees certainty about the exposure calculation used to determine the maximum permitted concentration. Option 2 has two methods that can result in significant discrepancies in the Margin of Safety (MoS), even when using the same data. Option 3 provides no certainty at all. This also means no scientific justifications are required by an applicant using Option 1, whereas Options 2 and 3 are likely to need justification to support the validity of the approach taken by the applicant. Justifications are often supported with literature or references to relevant guidance or data. A regulatory cost would only apply to an ingredient that has been shown to be absorbed through the skin. The exposure model is not relevant for assessing ingredients that are not absorbed through the skin, as there is no systemic exposure. Between 2021 and 2024, the TGA received only 3 applications to evaluate new ingredients for use in sunscreens that are absorbed and require consideration of exposure. As such, for the purposes of calculating the regulatory burden estimates and consistent with the OIA guidelines, the assumption is that over a 10-year period a total of 7.5 applications would be received.

The scenarios below are based on an ingredient evaluation failing due to the exposure calculation. This means a subsequent application for ingredient approval would be required because the proposed maximum concentration for the ingredient was not considered safe based on the exposure model calculation, not due to the quality of the application or any other factors. The scenario assumes the worst-case outcome where the ingredient is not approved because the exposure assessment is not agreed upon between the TGA evaluator and the applicant based on the guidance for each option.

The evaluation fees are based on the current TGA Fees and Charges Summary[26]. We are using the highest fee application, i.e. IN4, as most new sunscreen ingredients that are novel would require this category. An IN4 application has the maximum data requirement and is charged at $3,356 (Application fee) + $27,800 (Evaluation fee) = $31,156 total.

[26] www.tga.gov.au/how-we-regulate/fees-and-payments/summary-fees-and-charges/summary-fees-and-charges-applications-submitted-tga

## Cost of preparing new sunscreen ingredient application:

In the majority of cases the new substance applications received by the TGA are prepared and submitted by regulatory affairs consultants that are contracted by the sponsors (companies/industry). These consultants charge fees, based on the complexities associated with different aspects of the dossier, for the preparation of ingredient applications.

The TGA has contacted a network of regulatory affairs consultants to ascertain an average fee for preparing an ingredient application at the highest IN4 application category and tried to utilise that to establish relevant regulatory costs for the different options where varying level of uncertainties exist with regards to the appropriate exposure estimation.

Essentially, when uncertainties exist a justification based on scientific evidence/literature is required as per TGA's guidance for understanding the requirements for new substance applications. Briefly, a justification regarding the appropriate exposure calculation used should present how the requirement or guideline is met or addressed in a different way, in order for the application to be accepted by the TGA for evaluation and later suitable to assess the ingredient as safe or low risk. Supporting reasons for why the approach would be valid is normally required with full text citations of relevant papers if applicable. Justifications that are not complete and/or sound may result in an application being rejected after evaluation.

**Option 3 (Status Quo):**

For Option 3 we assume an initial justification would need to be provided based on good scientific information/literature for which exposure calculation is used as there is currently no formal guidance or exposure model adopted in Australia. It is assumed that a subsequent justification for further clarification during evaluation would need in the worst case to be.

Based on the information we have received from regulatory affairs consultants, an average cost of preparing a dossier under status quo (Option 3), with uncertainties around the appropriate exposure estimation to use, is approximately $45,000. This amount includes the cost of an initial justification which has been advised to be $2100, and $500 for a subsequent justification or clarification provided to the TGA if required. Therefore:

- the average cost of preparing a new ingredient application dossier under Option 3 is **$45,000**.
- the number of new ingredient (absorbed through the skin) applications submitted over a 10-year period = **7.5.**
- the total cost to industry for preparing new sunscreen ingredient applications averaged across a 10-year period would be: $(45,000 x 7.5)/10 = **$33,750** per year.

**Option 2:**

If using Option 2 (SCCS) we assume an initial justification would need to be provided because there is 5-fold variability in the Margin of Safety calculation between which SCCS exposure estimation method is used. However, it is assumed that a subsequent justification will not be required during evaluation for the purposes of comparing to Option 3 which has less regulatory certainty. Therefore:

- the cost of Option 2 is calculated as the average cost of preparing a new ingredient application dossier ($45,000) less the cost for providing a subsequent justification ($500) = **$44,500**.
- the number of new ingredient (absorbed through the skin) applications submitted over a 10-year period = **7.5**.
- the total cost to industry for preparing new sunscreen ingredient applications averaged across a 10-year period would be: $(44,500 x 7.5)/10 = **$33,375** per year.

**Option 1:**

No additional justifications will be required when using the ASEM (Option 1) as it provides one exposure estimate for a general sunscreen, suitable for the Australian context. Therefore:

- the cost for Option 1 is calculated as the average cost of preparing a new ingredient application dossier ($45,000) less the cost for providing an initial ($2100) as well as a subsequent justification ($500) = **$42,400**.

- the number of new ingredient (absorbed through the skin) applications submitted over a 10-year period = **7.5**.

- the total cost to industry for preparing new sunscreen ingredient applications averaged across a 10-year period would be: $(42,400 x 7.5)/10 = **$31,800** per year.

## Cost of submitting sunscreen ingredient applications (includes cost of subsequent applications due to failure to pass initial evaluation):

**Option 3 (Status Quo):**

For Option 3, the scenario considers a worst hypothetical scenario that the applicant chooses an exposure estimation method that the TGA evaluator does not consider is appropriate. This would result in a failed first application, thereby needing a subsequent application.

The calculations in this situation consider the number of new ingredient (absorbed through the skin) applications submitted over a 10-year period = 7.5, and the TGA fees for these applications, as well as engaging another regulatory affairs agent to submit the subsequent IN4 application.

It is assumed that the regulatory affairs agents' fees for compiling the subsequent application will be less than that for the initial application, as they will only need to compile the dossier with the same information and address the previously contested exposure value before resubmitting to the TGA. Hence a lower-level application preparation fee of **$10,000** will be used in the cost estimations.

The total cost to industry for submitting 2 applications per new sunscreen ingredient:

- Evaluation fee for each IN4 application x 2 + Regulatory affairs agent fee for each subsequent application x 3 =

  (7.5 x $31,156) x 2 = $467,340 + (7.5 x 10,000) = $75,000

  = **$542,340**.

- Average cost averaged across a 10-year period would be: **$54,234** per year.

**Option 2:**

For Option 2, the scenario considers a worst hypothetical scenario that the applicant chooses a less conservative SCCS exposure calculation (Method 1), whereas the TGA evaluator considers the higher exposure calculation is more appropriate (Method 2). This would result in a failed first application, thereby needing a subsequent application.

The calculations in this situation consider the number of new ingredient (absorbed through the skin) applications submitted over a 10-year period = 7.5, and the TGA cost of these applications, as well as engaging another regulatory affairs agent to submit the subsequent IN4 application.

It is assumed that the regulatory affairs agents' fees for compiling the subsequent application will be less than that for the initial application, as they will only need to compile the dossier with the same information and address the previously contested exposure value before resubmitting to the TGA. Hence a lower-level application preparation fee of **$10,000** will be used in the cost estimations.

The total cost to industry for submitting 2 applications per new sunscreen ingredient:

- Evaluation fee for each IN4 application x 2 + Regulatory affairs agent fee for each

subsequent application x 7.5 =

(7.5 x $31,156) x 2 = $467,340 + (7.5 x $10,000) = $75,000

= **$542,340**.

- Average cost averaged across a 10-year period would be: **$54,234** per year.

**Option 1:**

No subsequent application will be required for Option 1 as the ingredient is assumed to be approved during the first application using the ASEM which provides a clear and consistent outcome.

- The calculations in this situation consider the number of new ingredient (absorbed through the skin) applications submitted over a 10-year period = 7.5 and the cost of a single IN4 application.
- The total cost to industry for new sunscreen ingredient applications averaged across a 10-year period would be: (7.5 x $31,156)/10 = **$23,367** per year.

## Section 60 reviews based on an ingredient evaluations that were not approved:

Where an application is made under section 26BD of the *Therapeutic Goods Act 1989*, for a recommendation by the Secretary that the Minister vary the determination made under section 26BB of the Act (Permissible Ingredients Determination) to include a new ingredient, then a decision to refuse to make that recommendation is a reviewable initial decision under section 60 of the Act.

Applicants can request within 90 calendar days to review the decision and provide additional information for consideration. This process requires the Minister or the Minister's delegate (usually an Executive Level 2 delegate within the TGA) to undertake a review of the applicant's section 60 request, and provide notice in writing of the outcome within 60 calendar days after the request was made. If the delegate fails to give such notice within 60 days, the delegate is deemed to have confirmed the initial decision.

The calculations below consider the cost to Government (TGA) if an appeal is submitted and a delegate is required to consider the appeal through the section 60 process.

**Options 2 and 3:**

This scenario assumes Option 2 and 3 result in a worst case of unsuccessful first applications as calculated above, and the applicant chooses to submit a section 60 request.

- Total number of days for section 60 review = 60 days (2 months)
- Executive level 2 (EL2) time taken in hours to review = estimated as 30% of work hours
- Monthly rate for EL2 = $170,695/12 = $14,224
- Total cost = Monthly rate * 2 months * 30% = 14,224*2*0.3 = **$8,534 (per application/review)**
- Average over 10 years = ($8,534 * 7.5 applications)/10 = **$6,400.50 per year**

**Option 1:**

No section 60 reviews would be submitted as applications are assumed to be approved at the first submission using the ASEM.

- Average cost over 10 years = $0

## Cost to industry from delays in approval of ingredients:

Delays in approving an ingredient for use in sunscreens can lead to financial losses for industry stakeholders due to the delay in bringing products to the Australian market. Unfortunately, due to the

highly circumstantial nature of products, reliable information to estimate these costs was not available to the TGA or industry to accurately estimate.

While the regulatory cost calculations suggest a net saving for adopting Option 1, there could be a worst-case scenario where a delay in marketing a product with an ingredient that was refused in the first application (even if Option 1 was adopted), leads to impact to industry due to lost income from delayed access to the market. However, based on the current value and predicted growth of the sunscreen market in Australia, [27] it is expected that the industry should be able to absorb these costs. (Refer to the Value of the Australian sunscreen market below).

### Value of the Australian sunscreen market

The IBISWorld's 2023 market analysis[28] includes the 'Sunscreen and Other Skincare Product Manufacturing industry' as part of the wider 'Cosmetics, Perfume and Toiletries Manufacturing' industry. IBISWorld predicts that the revenue for 'Cosmetics, Perfume and Toiletries Manufacturing' in Australia is expected to grow at 3.4% annualised over five years to reach an estimated $695 million in 2028. The revenue for sun-care products industry (including sun block, after-sun products and self-tanning products) in 2023 was 97.3 million. If this industry grows at the same rate as the broader cosmetic industry (3.4% annualised over five years), it can be extrapolated that the 'Sunscreen and Other Skincare Product Manufacturing industry' will be worth approximately $115 million in 2028 and approximately $136 million in 2033.

Due to Australia's harsh climate and high UVR, sunscreen is perceived as an essential domestic product. Globally, Australian sunscreen is renowned for its high SPF quality, with several Australian sunscreen products having successfully penetrated international markets. Growing local and international consumer awareness of the damaging effects of sunlight is supporting local sunscreen manufacturers. In addition, emergent health, wellbeing and beauty trends, combined with higher prices, will contribute to the expected revenue growth.[29]

A key trend shaping the industry in recent years, has been the growing demand for skincare and suncare products free from chemicals like parabens, phthalates, sulphates, artificial preservatives, fillers and genetically modified plant derivatives. IBISWorld states that many local skincare manufacturers are successfully capitalising on growing consumer demand for natural or organic skin care products by leveraging the functional properties of Australian native botanicals.

Sunscreen and other skincare product manufacturing is characterised by a consistent stream of product launches. Technological advancements enable players to focus on higher value and innovative products targeted at both mass and premium markets. The continued shift towards niche and upscale products will benefit sunscreen and other skincare product manufacturers in the coming years[30].

IBISWorld states that skincare manufacturers differ substantially in size and product offerings, with many independent manufacturers, including family-owned companies and small-scale contract manufacturers. The industry has numerous small players that cater to specific markets and offer a variety of niche products, adding to the industry's fragmented nature. Sunscreen and skincare product manufacturing is predominantly located along the eastern seaboard. New South Wales, Victoria and Queensland account for over 80% of enterprises. In relation to retail sales, IBISWorld provides the following figures for the broader skin care industry and states that this trend is similar for the sunscreen industry:

- Online channels are the top retail market at $222.4 million worth of sales.
- Pharmacies, including large chains such as Chemist Warehouse at $208.5 million worth of sales.
- Grocery channels, such as Woolworths and Coles had $137.6 m worth of sales.

[27] https://www.statista.com/outlook/cmo/beauty-personal-care/sun-protection/australia

[28] IBISWorld Sunscreen and Other Skincare Product Manufacturing in Australia, IBISWorld Pty Ltd December 2023

[29] IBISWorld Sunscreen and Other Skincare Product Manufacturing in Australia, IBISWorld Pty Ltd December 2023

[30] IBISWorld Sunscreen and Other Skincare Product Manufacturing in Australia, IBISWorld Pty Ltd December 2023

- Department and specialty stores were the smallest retail market, with $126.5 m worth of sales.
- IBISWorld states that online retail sales for the cosmetic industry have surged in recent years. A marked rise in online sales during COVID-19 lockdowns boosted this market. As online sales continue to grow strongly, skincare manufacturers are launching new e-commerce platforms that sell directly to consumers. Many of these sites are single-brand sites, designed to control the company's image. Raw material costs are the single largest cost for skincare manufacturers. Wider consolidation trends in chemical supplier industries are having an impact on raw material availability and prices[31].

## Regulatory burden estimate (RBE) tables for all 3 Options:

Considering the above scenarios, the total regulatory costs, and subsequent change are presented for each option below.

Please note, these costs do not include the cost to the TGA arising from the s60 reviews/appeals.

The costs are based on average industry estimates and reflect the yearly cost over a 10-year period.

**Table 13: Regulatory burden estimate (RBE) for Option 3**

Average annual regulatory costs if **Option 3** is adopted, and all applications are approved using this option

| Change in costs ($) | Business | Community Organisations | Individuals | Total change in costs |
|---|---|---|---|---|
| **Total, by sector** | $87,984* | $0 | $0 | $0** |

* Total cost to industry = Cost of preparing application ($33,750) + Cost of submitting applications ($54,234).

** This is the current state, hence no change in costs reflected. Options 1 and 2 will be compared against this.

**Table 14: Regulatory burden estimates (RBE) for Option 2**

Average annual regulatory costs if **Option 2** is adopted, and all applications are approved using this option

| Change in costs ($) | Business | Community Organisations | Individuals | Total change in costs |
|---|---|---|---|---|
| **Total, by sector** | $87,609* | $0 | $0 | -$375 |

* Total cost to industry = Cost of preparing application ($33,375) + Cost of submitting applications ($54,234).

[31] IBISWorld Sunscreen and Other Skincare Product Manufacturing in Australia, IBISWorld Pty Ltd December 2023

**Table 15: Regulatory burden estimates (RBE) for Option 1**

Average annual regulatory costs if **Option 1** is adopted, and all applications are approved using this option

| Change in costs ($) | Business | Community Organisations | Individuals | Total change in costs |
|---|---|---|---|---|
| **Total, by sector** | $55,167* | $0 | $0 | -$32,817 |

* Total cost to industry = Cost of preparing application ($31,800) + Cost of submitting applications ($23,367).

Overall, based on the consideration of the regulatory costs both quantitative and qualitative, as highlighted above, Option 1 leads to the highest benefit with a net reduction in regulatory burden.

# 5. Who did you consult and how did you incorporate their feedback?

## Annual low-negligible risk consultation 2023-2024

In August 2023, the TGA initiated a public consultation to determine the safe levels of benzophenone (a degradation impurity) in sunscreens containing octocrylene. The assessment utilised the Cancer Council's full-day sunscreen application recommendation, equating to 140 mL for a full body, to calculate the maximum worst-case sunscreen exposure.

However, while one respondent supported the approach, industry feedback indicated that this estimate was overly conservative, not reflective of actual consumer usage and failed to consider additional protective measures advised by the Cancer Council.

Industry stakeholders presented varied perspectives on the appropriate method for exposure assessment:

- Many suggested adopting the SCCS's daily usage model of 18 g/day as the best available model at the time.
- Others proposed alternative volumes such as using 50 mL instead of 140 mL, or a daily estimate of 45 mL (5 mL for face and neck, 2.5 mL for forearms and lower legs, applied once before work/school, once at morning tea/recess and once at lunch) based on the Cancer Council’s policies for schools, acknowledging that the torso is not exposed most of the time and other protection measures are used.
- Others suggested based on sales data, divided by the Australian population, that consumers on average would use minimal sunscreen a year.

The diversity of opinions highlighted the need for further development of a suitable exposure model that aligns with Australian guidelines and practices. Some stakeholders welcomed further work to consider an appropriate exposure model based on Australian guidelines.

As such, in response to industry stakeholder feedback, the TGA advised in December 2023 that it would consider developing a sunscreen exposure model for the Australian context with future

consultation to be undertaken. The proposed changes regarding setting an acceptable regulatory limit for benzophenone were deferred pending consultation.

## Targeted consultation

The TGA undertook targeted pre-public consultation, with most stakeholders supporting the proposal to develop an Australian specific sunscreen exposure model. The TGA engaged with the following groups to request preliminary feedback and seek information to assist with developing the ASEM:

- Industry peak bodies and their member companies:
  - Accord Australasia
  - Consumer Healthcare Products Australia (CHP Australia)
- Non-government organisations:
  - The National Skin Cancer Committee, which includes the Cancer Council Australia members at the national level, and member representatives from organisations that have an interest in skin cancer and prevention such as the Bureau of Meteorology and Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).
  - Melanoma Institute Australia
  - The Australian Skin and Skin Cancer Research Centre, a partnership of QIMR Berghofer Medical Research Institute and The University of Queensland
  - The Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
  - The Australasian College of Dermatologists (ACD)
  - Surf Life Saving Australia
  - CHOICE
  - Consumers Health Forum of Australia
- Australian Government:
  - Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)
  - Australian Industrial Chemicals Introduction Scheme (AICIS)
  - Safe Work Australia
  - The Australian Bureau of Statistics (ABS)
  - Department of Health and Aged Care (DOHAC) - Cancer Policy and Projects Branch

The TGA has been in regular consultation with Accord and CHP Australia throughout the process of developing the ASEM. Accord is the national industry association representing manufacturers and suppliers of hygiene, personal care and specialty products, their raw material suppliers and service providers. CHP Australia is the peak body representing manufacturers and distributors of consumer healthcare products, which includes non-sunscreens. They also represent businesses that support the industry.

Industry peak bodies had some initial concerns that some of the early draft exposure scenarios were too conservative and could restrict sunscreen ingredients unnecessarily. The TGA invited and considered feedback to refine the ASEM and exposure scenarios. Specific issues raised were

considered and responded to, and later discussed in the public consultation paper to clarify the data and assumptions used in the modelling.

As sunscreen ingredients can also be present in cosmetic products, and cosmetic sunscreen ingredients are regulated by AICIS, the TGA consulted with AICIS on the ASEM and consultation paper. AICIS provided feedback, to better clarify the purposes of consultation and ASEM for conducting risk assessments for ingredients in therapeutic sunscreens (i.e. those that are intended to prevent skin cancer and applied liberally by the whole family), not non-therapeutic products (such as cosmetic foundations used on the face that may contain ingredients that have an SPF rating). The TGA worked closely with AICIS through the consultation process.

Safe Work Australia and Cancer Council South Australia provided the TGA with unpublished Australian research on sunscreen use habits in outdoor workers and children in early learning centres across Australia. The research provided real world evidence on the sunscreen use practices, and the findings from the Cancer Council were used to refine the exposure scenarios in the ASEM and develop the highest estimated daily sunscreen exposure in toddlers presented in Option 1 in the public consultation paper. The research was discussed in the public consultation paper as supporting evidence for the ASEM for all stakeholders to consider.

The ARPANSA and the Cancer Council Australia members recommended modifications to some of the draft exposure scenarios used in the ASEM to reflect common scenarios in outdoor workers wearing shorts and t-shirts as they may not always wear long sleeves. They also highlighted that younger children often have more sunscreen use, than older children, particularly as parents and carers may protect them even if they don't apply sunscreen themselves, noting the unpublished research in early learning centres from the Cancer Council South Australia. The TGA refined the ASEM exposure scenarios in accordance with this feedback. They also recommended that the TGA speak to occupations with high UVR exposure such as surf life savers in QLD, and the TGA later contacted Surf Life Saving Australia.

Surf Life Saving Queensland, on behalf of Surf Life Saving Australia, provided information on the occupational conditions, clothing, shade, and sunscreen use for surf life savers. This information was used to ensure the ASEM exposure scenarios covered sunscreen use from heavy users who are exposed to higher UVR conditions on a more regular basis.

ASCEPT advised that it would be more helpful to have a simpler approach to using the ASEM as a tool rather than a complex table with specific populations needing to be considered. The TGA refined the ASEM to derive a single exposure value that would be used for regulatory purposes (the highest estimated average daily sunscreen exposure in toddlers). This was presented in the public consultation paper.

The ACD noted that sunscreen should be used as last line of defence for infants aged 6-12 months, after applying clothing and staying out of the sun, and questioned if the ASEM factored in that less sunscreen would be used in that age group. The TGA considered this feedback, and ensured the highest exposure scenario for children (scenario 3) presented in the public consultation paper specifically excluded infants under 12 months noting they are not recommended to be exposed to the sun and children under 6 months are not recommended to use sunscreen.

The ABS advised that they had recently conducted a Sun Protection Behaviours survey to assess the sun protection habits of Australian adults and adolescents from November 2023 to February 2024. The results were released on 3 September 2024 and the survey revealed that 38.1% of Australians aged 15 years and over used SPF 30 or higher sunscreen on most days in the last month of the survey period. Additionally, 60.6% of Australians spent more than 15 minutes outdoors during peak UV times and more people spend time outdoors during peak UV hours on weekends compared to weekdays. When compared to a similar survey conducted by Cancer Council Australia between 2003 and 2017, the ABS survey showed an increase in the use of sunscreen as a sun protection measures (49.4% vs. 42%). The sun protection behaviours reported in this survey aligned with the assumptions and parameters used in the ASEM.

CHOICE and Consumers Health Forum of Australia did not provide comment.

# Public consultation July – August 2024

Between July and August 2024, the TGA published a public consultation regarding creating a model that more accurately estimates how much sunscreen Australians are exposed to on a regular basis. The model was proposed to enable the TGA to calculate the safe concentration of ingredients in sunscreens based on Australian conditions and the latest scientific information.

The consultation included 3 proposed options:

- Option 1: Australian Sunscreen Exposure Model (ASEM)
- Option 2: Scientific Committee on Consumer Safety (SCCS) exposure model
- Option 3: Status quo

A total of 28 submissions were received from the therapeutic goods and cosmetic industry (industry organisations, sponsors, and manufacturers), non-profit organisations, universities, government organisations, health professional organisations, and individuals.

**Preferred option**

There was broad in-principle stakeholder support for the adoption of the ASEM (Option 1) for estimating sunscreen exposure when conducting sunscreen ingredient risk assessments. No respondents supported Option 3 and only 3 respondents (primarily European cosmetic industry associations) preferred Option 2.

Although there was general support for Option 1, some respondents did not agree with all its elements. A number of respondents (three) proposed amendments that would make the assessment less conservative and more flexible, while others (four) suggested changes to make the assessment more conservative.

These comments are elaborated upon below and were taken into consideration in the refinement of the model.

**Importance of consistency of regulatory assessments and outcomes**

Industry respondents emphasised the need for innovators and manufacturers of sunscreen ingredients to have confidence that the data they generate is consistent across all sunscreen regulators. One response highlighted that the calculations and assumptions for the ASEM formula require the same safety data inputs as the SCCS exposure model. This consistency supports innovators of new ingredients by allowing them to provide data that meets the requirements of different agencies.

Some respondents also commented on the Margin of Safety (MOS) calculations presented for the ASEM, noting that it generally produces congruent results, which increases confidence in their reliability. In contrast, they pointed out that the way dermal absorption data is presented can significantly affect the MOS calculations (up to 5-fold) in the SCCS exposure model.

The TGA notes that the ASEM, and the highest estimated exposure value, provides the greatest regulatory consistency for risk assessments compared to the other options proposed in the consultation paper. This consistency can better support innovation and development of sunscreen ingredients. However, the ASEM can be capable of being flexible, accommodating for different product types if required which was also identified as important by some respondents.

**Flexibility of risk assessments using the ASEM**

Multiple industry respondents recommended that flexibility should be available when utilising the ASEM in the safety assessment of sunscreens designed for specific product types such, such as facial sunscreens, which are used primarily for the face unlike general primary sunscreens. One

respondent noted the use of these products is consistent with Scenario 1 (indoor worker) presented in the consultation paper, and these products are packaged in smaller volumes.

The TGA acknowledges the merit in utilising the ASEM tool to consider a usage scenario for sunscreens that are not intended for general use. Further consideration will be given to establishing a standardised exposure assumptions to be included in future guidance, and what risk management and presentation requirements may be needed to ensure such products are used as intended.

**Sunscreen application rate of 2 mg/cm$^2$ used in the ASEM**

The majority of respondents agreed with the calculations and assumptions used in the ASEM formula, which includes the application rate of 2 mg/cm$^2$ that is required to achieve the labelled SPF rating.

Some industry respondents suggested that the 2 mg/cm² application rate does not reflect real-world consumer behaviour, highlighting that consumers typically apply sunscreen at lower rates. Two of these respondents recommended 1 mg/cm$^2$ be used as the application rate. These respondents quoted five studies, including 3 Australian studies already discussed in the consultation paper, and 2 older European studies (conducted outside Australia), highlighting the median or mean application were less than 2 mg/cm².

The consultation paper emphasised that one of the guiding principles was to ensure the adopted model accounts for correct usage directions for effective sun protection and this will not be achieved with application rates less than 2 mg/cm$^2$. Moreover, the ASEM assumptions were constructed to reflect the higher end of sunscreen usage in Australia, rather than the average Australian's usage. This approach was taken to ensure that the risk assessments for sunscreen ingredients, when based on the highest usage scenarios, will also guarantee safety for lower usage cases where less of the ingredient may be applied to the skin.

The TGA acknowledges that not all consumers apply sunscreen at the thickness to achieve the labelled SPF; however, the same Australian studies quoted, and discussed in the consultation paper, support that there are Australians that would apply at 2 mg/cm$^2$ or more. The European studies quoted are conducted outside of Australia and may not reflect the unique conditions and practices in Australia today for the reasons described in depth in the consultation paper. An application rate of 2mg/cm$^2$ is needed to cater for Australians who use sunscreen at the application rate of 2mg/cm$^2$ and those that use less, to ensure that sunscreen ingredients are both safe and effective when used as directed.

**Clarification of sunscreen exposure calculations for the 'highest estimated daily exposure'**

One respondent supported the ASEM if the TGA seeks to calculate the upper band of annual average daily sunscreen exposure in the Australian population, noting the ASEM offers a plausible and defensible measure, based on current evidence. However, this respondent disagreed that the ASEM calculates the maximum dose of sunscreen that could be applied in one day, as it averages exposure over the course of a year based on weekly patterns, underestimating the potential maximum exposure in a single day.

The TGA wishes to clarify that the ASEM calculates the upper band of annual average daily sunscreen exposure in the Australian population, based on current Australian evidence and guidelines. Risk assessments for sunscreen ingredients typically focus on long-term exposure, however, any acute toxicity concerns are still considered in the risk assessment, and this would still utilise the maximum expected dose that could be applied in one day for a sunscreen used for whole-body application (140 mL).

**Some Australians may use more sunscreen than proposed in some scenarios**

One respondent recommended that the TGA increase the duration from 26 days to 52 days for Scenario 6 to account for the lifestyle of residents in beach-side communities in northern Australia. Another respondent noted that in high-performance sports, there is often a deliberate strategy of training during the hottest part of the day, when UV exposure is likely to be high. Further, the culture regarding the use or non-use of sun-smart clothing varies between different sports. For example,

some sports, such as beach volleyball and canoeing or rowing, involve a high degree of UV exposure with minimal sun-smart clothing.

The highest average daily sunscreen exposures as established by the ASEM is 673 mg/kg bw/day or 336 cm²/kg bw/day which broadly covers the majority of different scenarios and populations. As an example, if the duration for Scenario 6 is extended from 26 days to 52 days as suggested, the highest average daily sunscreen exposure for adults across a year (i.e. Scenario 4 + 6) would be 408 mg/kg bw/day or 204 cm²/kg bw/day, which is still less than 673 mg/kg bw/day or 336 cm²/kg bw/day. As such, the 673 mg/kg bw/day or 336 cm²/kg bw/day exposure values would still ensure safety of ingredients for these circumstances.

**Exposure assumptions for toddlers**

Some industry respondents supported the ASEM scenarios but had concerns about the assumptions made in establishing the highest estimated average daily sunscreen exposure for toddlers aged 1-2 in Scenarios 3. These respondents suggested that toddlers would not have enough sun exposure requiring 3 applications of sunscreen a day (as per Scenario 3) due to typical daily schedules that include naps, eating, baths and indoor play. Instead, they suggested 1-2 applications of sunscreen daily were more realistic.

As discussed in the consultation paper, 3 sunscreen applications per day for Scenario 3 was derived from Australian research reporting on actual sunscreen practices followed by 1,189 Australian SunSmart early childhood centres, surveyed in the 2018 National Early Childhood Sun Protection Policy and Practice Survey. It should also be noted that the study revealed a proportion of services (ranging from 4-20% across Australia) also applied sunscreens 4 times a day, however this frequency was not utilised in Scenario 3 as it would likely result in an overestimation of majority practice. The calculations used in the ASEM were based on empirical evidence rather than assumptions relating to periods of daily sun exposure or generalised routines. Additionally, sunscreen application frequency does not necessarily correlate with total time exposed to the sun i.e. smaller individual time periods of sun exposure when the UV index is 3 or above (which can be year-round in parts of Australia) may necessitate multiple sunscreen applications for each period of sun exposure.

Some respondents expressed concerns about the assumptions made in establishing the highest estimated average daily sunscreen exposure in Scenario 5, suggesting that one day a weekend may not sufficiently reflect the highest use case and that sun protective clothing portrays recommended behaviour rather than what may be observed. The TGA appreciates that the perception, or reality, may differ from the assumptions of the ASEM scenarios, as they are also designed to account for Australian recommendations and public health messaging rather than solely habits and practices. This provides a standardised approach to ensure regulatory certainty. The currently proposed highest estimated average daily sunscreen exposure is based on a high use situation in toddlers (annually) which provides a conservative estimate that is sufficient to cover for variability in sunscreen use among different population groups. The TGA observes that even slight modifications to Scenario 5 would not have a significant impact on the overall exposure values, as Scenario 3 (which already accounts for short clothing and 3 application per day across 240 days) constitutes the predominant exposure for toddlers annually.

Considering the reasons above, and that the majority of respondents agreed with the highest estimated average daily sunscreen exposure calculations, ASEM assumptions and ASEM scenarios, the TGA has maintained the overall exposure estimates for the Scenarios.

**Flexibility of the ASEM compared with the SCCS**

One respondent commented that the ASEM is a good model with clear rational and accurately reflects consumer use of sunscreens. However, they preferred the SCCS model (Option 2), suggesting it is more flexible than the ASEM. They assumed the ASEM would be legislated and could not be updated if scientific information changes, potentially making the methods used obsolete, unlike the SCCS model, which is provided as guidance.

The TGA wishes to clarify that, as stated in the consultation paper, the exposure calculations derived from the ASEM will be included in the Australian Regulatory Guidelines for Sunscreens not legislation.

The ASEM can also be flexible to accommodate for new usage scenario (as described above for facial sunscreen products).

**Weather assumption used in ASEM scenarios**

Four respondents recommended that the TGA consider extreme and/or above-average temperatures when estimating the days sunscreens are being used in Scenarios 5 and 6. These respondents noted that most outdoor activity occurs during the winter months in northern Australia, while acknowledging the ASEM calculations may not change.

While the exposure calculations were calculated for one day each weekend over a 6-month period from October to April, a similar time period may be considered for other regions in winter months due to less extreme weather. As noted, this amendment would not alter the ASEM calculations.

**Barriers to trade**

Some industry respondents raised concerns that Australian-specific assessments could create trade barriers for European products. Different allowable concentrations in various countries may impact the supply of certain ingredients. These respondents emphasised the need to ensure a sufficient range of sunscreen active ingredients to formulate very high SPF products without compromising safety.

The consultation paper highlighted the differences between Australian environmental and cultural conditions and the regulatory framework for sunscreens compared to Europe. It stressed the importance of having an assessment process tailored to Australia's needs. Given that Australia has the highest incidence of skin cancer in the world, sunscreens designed primarily for UV protection are regulated as therapeutic goods with different compliance standards, unlike some sunscreens overseas that may be regulated as cosmetics. These differences can affect conclusions about the safety of ingredients, including approval of higher permitted concentrations in Australia compared to other countries. In contrast, alignment of international assessments may sometimes result in reduced availability of safe sunscreen ingredients in Australia. To ensure safe sunscreen active ingredients are not restricted from being used in Australian products, the TGA makes regulatory decisions following a careful analysis of the latest scientific evidence, tailored to Australia's distinct environmental conditions, health requirements, and regulatory framework.

**Clarity on preferred method used when dermal absorption is reported as both proportion (%) and absolute amount (µg/cm$^2$)**

Several respondents sought clarification on which method of the ASEM will be used when dermal absorption data is provided as both a % and µg/cm$^2$. These respondents emphasised the need for clear rules to determine which method will be used.

The choice of dermal absorption factor and method of calculation (i.e. Method 1 vs Method 2) depends on the type and quality of the data available for establishing the dermal absorption potential of the ingredient under consideration. In general, there is no preference for use of Method 1 or Method 2 as the ASEM approach results in the same risk quantification (i.e. same MoS values) irrespective of whether dermal absorption is quantified in µg/cm² (Method 2) or as a percentage (Method 1) when the test formulation is applied at a thickness of 2 mg/cm$^2$ in the dermal absorption study (compliant with OECD 428 – Guideline for Skin Absorption: *in vitro* method).

Dermal absorption studies (compliant with OECD 428) typically express results as both an absolute amount (i.e. µg/cm²) and a relative amount (percentage) and stipulate an application rate of 1-5 mg/cm² to mimic realistic human exposure. While 2 mg/cm² is the thickness of applied sunscreen needed to achieve the labelled SPF rating, studies often apply the test formulation at 3, 4, or 5 mg/cm² instead. The SCCS notes for guidance for testing of cosmetic ingredients (12$^{th}$ Rev) also state that *in vitro* measurements using less than 2 mg/cm² are not technically feasible. The SCCS guidance on basic criteria for the in vitro assessment of dermal absorption recommends a 2-5 mg/cm$^2$ dose of test formulation. This can cause variability in the risk quantification (i.e. MoS calculation) between Method 1 and 2 since the reported absolute amount absorbed will be a different percent of 3, 4, or 5 mg/cm² application rate versus that of a 2 mg/cm² application (as highlighted in Attachment 3 of the consultation paper).

Where an application rate greater than 2 mg/cm$^2$ is used in the dermal absorption study, the absolute amount (µg/cm$^2$) may be used when calculating the systemic exposure for risk assessments in order to minimise this variability. This is particularly important since it is known that the efficiency of absorption may remain the same or change as the concentration on the skin increases for some chemicals. For chemicals that penetrate the skin rapidly, the total amount of chemical absorbed increases as the dosage increases. Conversely, for chemicals that penetrate very slowly, the rate of penetration and the surface area exposed will have a greater influence on the systemic absorption dose than the extent of dermal deposition.

Since the efficacy of sunscreen ingredients relies predominantly on their ability to persist on the skin (including the top layers of the skin), they are likely to penetrate very slowly (or ideally not penetrate). Suggesting that the total amount of chemical systemically absorbed may not be proportional to the dermal dose/deposition. Hence using the dermal absorption factor expressed as a proportion (i.e. %) may not be appropriate for some sunscreen ingredients.

**Clarity on use of annual average instead of lifetime average for daily dose calculations**

Some respondents queried why an annual average daily dose was calculated instead of a lifetime average daily dose in the ASEM. These respondents did not express a preference for either calculation method. Estimating sunscreen use is highly complex, as sunscreen use patterns vary among individuals based on several factors as discussed in detail in the consultation paper. A yearly model was utilised to account for the variability across weekday and weekend activity, and annual weather conditions. It is important to note, that while the ASEM calculates average daily exposure based on an annual sunscreen use pattern, this still allows for risk assessments that ensure safety of long-term sunscreen use throughout life.

**Other comments**

A number of comments were received about the risk assessment process, such as the MOS calculations and pharmacokinetic considerations. These are part of the risk assessment process and are separate to the external sunscreen exposure modelling proposed in the consultation. However, these matters are considered during the risk assessment and depend on the available data. Further guidance is proposed to be included in an update to the ARGS to clarify queries received in this consultation.

**Summary of TGA response**

Stakeholder feedback from the extensive targeted and public consultation has enabled refinement of the ASEM and shaped the options proposed in this paper.

Following pre-consultation, where stakeholders agreed on the need to develop an Australian-specific model, the TGA conducted extensive consultations to gather stakeholder views. During these consultations, the SCCS model was considered, due to stakeholders operating both in the European market and Australia. However, there was broad agreement among stakeholders that the Australian Sunscreen Exposure Model was preferred. Notably, the TGA is unaware of any alternative models, and stakeholders did not provide any alternative models in their consultation responses.

The TGA has considered all of the submissions and diverse stakeholder views, particularly noting the ability for increased flexibility that allows the ASEM tool to be used for future risk assessments of different product types, such as face-only sunscreens.

# 6. What is the best option and how will it be implemented?

## Preferred option

The TGA considers that Option 1 (ASEM) is the preferred option. There was broad in-principle stakeholder support for the adoption of the ASEM (Option 1) for estimating sunscreen exposure when conducting sunscreen ingredient risk assessments. No respondents supported Option 3 and only 3 respondents (primarily European cosmetic industry associations) preferred Option 2.

Option 1 provides the greatest qualitative reasons for adoption compared to the other two options. The ASEM provides the greatest regulatory certainty and consistency of evaluations for industry and ensures sunscreens are evaluated for safety based on Australia conditions.

The consistent methodology provided by the ASEM should result in evaluations being less likely to be challenged/contested, which will reduce the time and resources expended by applicants. This reduces potential delay of the introduction of new sunscreen ingredients and reduces burden on the regulatory process from unnecessary contention.

Certainty about the concentration that may be approved by the TGA is also likely to support innovation and development of new sunscreen ingredients given the lengthy research and development process required to bring new ingredients to market, with tests that may need to be conducted at the proposed concentration for final products.

An agreed estimated daily sunscreen exposure value means there is a standardised method for evaluating sunscreen ingredients, reducing discrepancies in risk assessments, meaning the same ingredient is not approved in one case and refused based on the same data in another case due to the use of differing methods. This levels the playing field for industry, whilst also ensuring ingredients are not unnecessarily prevented from entering the Australian market.

Further, as the ASEM is based on current scientific evidence and ensures safety by accounting for the way Australian's use sunscreens (including both children and adults) and aligns with how they should be used correctly based on current recommendations, the implementation of the ASEM will bolster confidence in sunscreen regulation and increase Australian's trust to use sunscreen as a daily UVR protective measure for the entire family. This in turn supports Government, health professional, academic, and industry efforts to promote the use of sunscreen as a tool in preventing against the tragic outcomes of skin cancer in Australia. This is particularly important as Australia has the highest incidence of melanoma and non-melanoma skin cancer incidence rate in the world.[32]

The consultation paper proposed that as part of Option 1, the highest estimated average daily sunscreen exposure value would be used for sunscreen safety assessments. This approach would ensure that ingredients assessed under this exposure assumption for the highest risk category which are toddlers aged 1-2, would also cover the safety in the rest of the population, which was supported by most respondents. However, the TGA will use the ASEM flexibility as well in line with industry stakeholder feedback, to conduct assessments for other types of sunscreens as necessary – such as those intended for face-only application in small containers, vs those intended for application to the body.

Further, Option 1 (ASEM) is the preferred option because, unlike Options 2 and 3, it achieves the following objectives:

- **Correct usage directions for effective sun protection**: The model integrates evidence-based application guidelines to achieve the labelled SPF rating, ensuring sunscreen ingredients are safe

[32] International Agency for Research on Cancer – IARC (1992). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. [online] Available at: https://www.ncbi.nlm.nih.gov/books/NBK401588/. [Accessed on 20 June 2024].

and effective when used as directed. It will be future proofed where possible to account for future expected sunscreen use based on current and emerging evidence-based recommendations.

- **Highest realistic use-case**: The model caters for the way sunscreen is used by the average Australian, as well as those who use sunscreen more frequently in realistic everyday scenarios, such as outdoor workers in northern Queensland where the UV index is very high all year round.
- **Contemporary evidence-based information**: The exposure model considers data reflective of the demographics that use sunscreens, such as children and adults, and the contexts in which sunscreen is applied, including areas not covered by clothing, with a preference for Australian-specific data where available.
- **A standardised approach for regulatory certainty**: The model offer a standardised, evidence-based methodology, that is practical for applicants and evaluators to assess ingredient risk, providing clarity and consistency for industry stakeholders and ensuring that sunscreens evaluations account for Australian use.
- **Upholding sunscreen safety and trust**: The model bolster the safety reputation of Australian sunscreens, ensuring consumers are confident in their evaluation by the TGA and encouraged to use them without fear or doubt.

A comprehensive exposure model promises greater assurance of sunscreen safety, accounting for long-term and cumulative exposure. This initiative aligns with growing consumer demand for transparency and safety in personal care products, fostering greater confidence in the market.

# Implementation plan

Adoption of the ASEM (Option 1), is considered the best out of the 3 considered, and will be a decision of a delegate of the Secretary of the Department of Health and Aged Care, as informed by this IA. The TGA anticipates that this decision will be made in November 2024, the stages of implementation, risks and mitigation measures are provided below.

**Table 16: Implementation Plan**

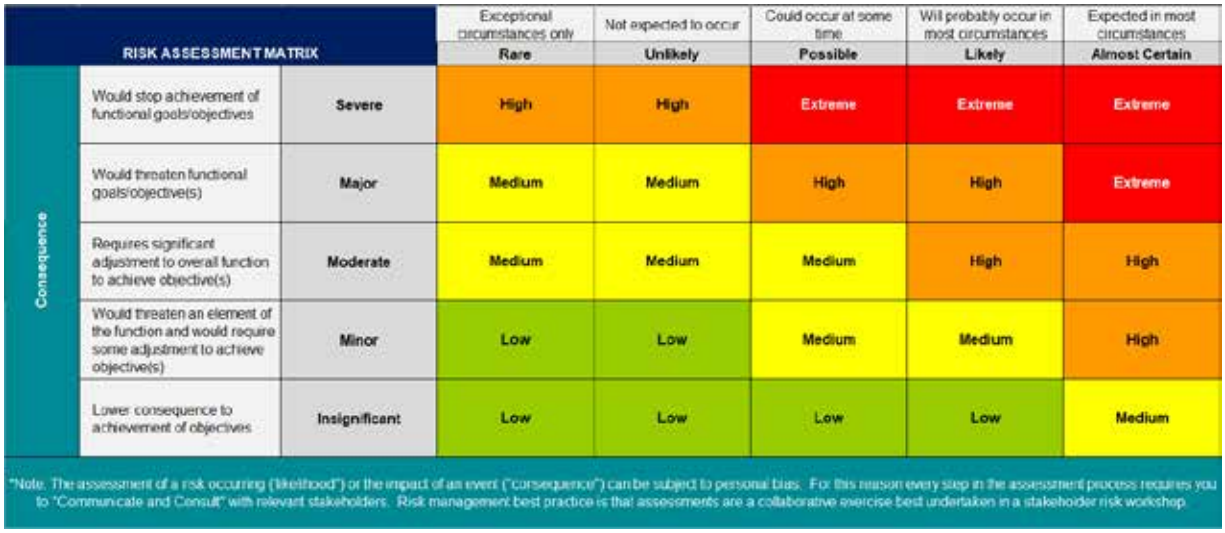
| Date | TGA Action |
|---|---|
| **November 2024** | 1. Proposed decision to adopt the ASEM |
| **December 2024** | 1. Consultation outcomes published on website<br>2. Industry will be advised on website and in the Australian Regulatory Guidelines for Sunscreens (ARGS) that all new sunscreen ingredient evaluations will be evaluated using the ASEM.<br>3. Draft of update to the ARGS with information about how to use the ASEM for new ingredient applications provided to sunscreen industry peak bodies, Accord and CHP Australia for review prior to publication. Guidance will apply to assessments where an ingredient can absorb through the outer layer of the skin (the stratum corneum) and can lead to systemic absorption. The final model will not be applicable to ingredients that are not absorbed beyond the stratum corneum or do not have the potential for systemic exposure. |
| **January 2025 onwards** | 1. The TGA will engage with new sunscreen ingredient applicants, including by offering free pre-submission meetings to discuss potential applications and provide guidance to assist applicants prior to submission. |

| Date | TGA Action |
|---|---|
| | 2. The TGA will continue to consult with peak industry bodies, Accord and CHP Australia regarding review of the ARGS before an updated version is published on the TGA website. |

## Implementation risks and mitigation measures

The ASEM (Option 1) provides estimations of sunscreen use based on Australian evidence-based recommendations and best available research to date. The implementation risks are outlined in table 17 and have been categorised by the Department of Health and Aged Care's Risk Assessment Matrix (Figure 4).

**Figure 4: The Department of Health and Aged Care's Risk Assessment Matrix**



| RISK ASSESSMENT MATRIX | | | Exceptional circumstances only | Not expected to occur | Could occur at some time | Will probably occur in most circumstances | Expected in most circumstances |
|---|---|---|---|---|---|---|---|
| | | | Rare | Unlikely | Possible | Likely | Almost Certain |
| Consequence | Would stop achievement of functional goals/objectives | Severe | High | High | Extreme | Extreme | Extreme |
| | Would threaten functional goals/objective(s) | Major | Medium | Medium | High | High | Extreme |
| | Requires significant adjustment to overall function to achieve objective(s) | Moderate | Medium | Medium | Medium | High | High |
| | Would threaten an element of the function and would require some adjustment to achieve objective(s) | Minor | Low | Low | Medium | Medium | High |
| | Lower consequence to achievement of objectives | Insignificant | Low | Low | Low | Low | Medium |

*Note. The assessment of a risk occurring (likelihood") or the impact of an event ("consequence") can be subject to personal bias. For this reason every step in the assessment process requires you to "Communicate and Consult" with relevant stakeholders. Risk management best practice is that assessments are a collaborative exercise best undertaken in a stakeholder risk workshop.*

**Table 17: Implementation risk, rating and mitigation measures**

| Risk description | Consequence | Likelihood | Rating | Mitigation |
|---|---|---|---|---|
| If actual comprehensive Australian sunscreen use data or further research is conducted, this could provide more robust information to model the estimating highest-use exposure in the Australian context. This may necessitate re-review of the ASEM which could require analysis and consultation. | Moderate | Unlikely | Medium | This is unlikely however, as gathering such extensive data that would be statistically representative of all Australians poses challenges. The TGA will continue to collaborate with relevant interested stakeholders on sunscreen issues to review the evidence should this arise. |
| If there are technological advancements, changes in public behaviour, alternative sunscreen use guidelines, and new international risk assessment methods, this could also question the | Major | Possible | High | The TGA will maintain a watching brief in this area to determine if future revisions to the ASEM would be necessary, and to ensure that the ASEM remains fit for purpose. |

| Risk description | Consequence | Likelihood | Rating | Mitigation |
|---|---|---|---|---|
| validity of the ASEM and require review. | | | | |
| The formal adoption of ASEM would not align with international jurisdictions that use the SCCS estimation of sunscreen use for risk assessments. This could lead to discrepancies where certain sunscreen ingredients are permitted overseas but restricted or limited to lower or higher maximum concentrations in therapeutic sunscreens in Australia and perceived by some industry stakeholders as a potential barrier to trade. | Minor | Likely | Medium | However, this also is currently the case, as sunscreens are regulated as therapeutic goods in Australia, and as such, have different regulatory requirements compared to overseas jurisdictions where these goods are regulated as cosmetics. Furthermore, use of the SCCS estimation is based on two methods depending on how dermal absorption data is reported, and this was discussed in detail the consultation paper to demonstrate that there could be significant differences in the risk assessments between each method. As such, even if the SCCS method was adopted in Australia, this could still result in significantly different risk assessments depending on the method used in the SCCS method. |

## Impact Analysis development

The table below (table 18) documents the development if the IA in relation to major decision points in the process.

**Table 18: Impact Analysis decision points and timelines**

| Decision point | Timeframe | Status of the IA |
|---|---|---|
| Consider whether a sunscreen exposure model can be developed for the Australian context[33] | December 2023 | Not commenced |
| Internal pre-consultation | January 2024 – May 2024 | Not commenced |
| External pre-consultation: Key stakeholders | May 2024 – June 2024 | Not commenced |
| Public consultation opened | July 2024 | Not commenced |
| Public consultation closed | August 2024 | Under development |
| Assess feedback from consultation | August 2024 | Under development |
| Draft ASEM outcome | September 2024 – November 2024 | Under development |

[33] https://consultations.tga.gov.au/medicines-regulation-division/low-neg-risk-2023-2024/user_uploads/cmes---low-negligible-risk-annual-consultation---2023-2024---final-decisions-document.pdf

| Decision point | Timeframe | Status of the IA |
|---|---|---|
| IA submitted to the OIA for 1st Pass assessment | September 2024 | 1st Pass assessment of IA completed |
| OIA 1st Pass assessment comments addressed in the IA and IA submitted to the OIA for 2nd Pass Final assessment | November 2024 | IA presented to OIA for 2nd Pass assessment |
| Final ASEM and IA published | December 2024 | To be informed by an IA that has been assessed by the OIA |

# 7. How will you evaluate your chosen option against the success matrices?

Continuous assessment will follow the adoption of Option 1 as the preferred model for risk assessments for sunscreen active ingredients. The monitoring and evaluation plan, detailed in table 19, will be conducted both continuously and at scheduled intervals. This will be carried out by the TGA, with ongoing collaboration with domestic regulators and agencies, and industry peak bodies.

**Table 19: Evaluation plan for adopting the Australian Sunscreen Exposure Model**

| Evaluation criteria | Responsibility | Relevant data | Timeframe |
|---|---|---|---|
| **Peak industry bodies to provide an update to the TGA at the TGA's Industry forum (Complementary and OTC Medicines Regulatory and Technical Consultative Forum)**<br>Specific agenda item at ComTech meeting in mid 2025-2026 to discuss adoption of the ASEM. Industry to provide feedback from applicants/agents outlining their experience regarding interpretation of the ASEM and updated ARGS. Industry can provide feedback if there have been quantitative changes in dollar value /time required to complete an application that could be attributed to using the ASEM, as this information was not able to be provided during development of the IA. | Industry peak bodies | Analysis of Member feedback. | Yearly over a five-year period, and ad-hoc feedback can be provided if issues arise. |
| **Stakeholder engagement/feedback**<br>The TGA will consider any feedback from applicants for new ingredients and TGA evaluators, regarding whether the ARGS guidance is clear about the risk assessment process and the ASEM is easy to understand and use.<br>Negative feedback could indicate the guidance requires revision to ensure the ASEM is easy to use and supports ingredient applicants to understand the process. The aim will be to understand if the ASEM has made the evaluation process clearer and easier to follow. | TGA | Analysis of evaluator and applicant feedback. | At end of an ingredient evaluation. |
| **Overseas regulators and other models**<br>The TGA will continue to monitor developments with other overseas regulators (such as the SCCS | TGA | Periodic review of overseas regulators web | Ongoing |

| Evaluation criteria | Responsibility | Relevant data | Timeframe |
|---|---|---|---|
| and US FDA) and internationally, on matters relating to safety of sunscreen ingredient assessments.<br>Any new models or risk assessment approaches will be considered and inform whether the ASEM is still fit for purpose. | | publications/guidance. | |
| **Numbers of new ingredient applications**<br>The TGA will monitor how may new sunscreen ingredient applications are received and compare this to application numbers prior to adopting the ASEM over the next 5 years, noting that application numbers can vary based on a range of other factors that may not be related to the ASEM. Higher application numbers could indicate more confidence in the regulatory assessment process. | TGA | Recording number of applications accepted for evaluation before and after ASEM. | Yearly over a five-year period. |

# Key Terms

| Abbreviation | Explanation |
|---|---|
| ABS | Australian Bureau of Statistics |
| AICIS | Australian Industrial Chemicals Introduction Scheme |
| ARGS | Australian Regulatory Guidelines for Sunscreens |
| ARNS | Application Requirements for New Substances in listed medicines |
| ARPANSA | Australian Radiation Protection and Nuclear Safety Agency |
| ASEM | Australian Sunscreen Exposure Model |
| ASSC | Australian Skin and Skin Cancer Research Centre |
| BoM | Bureau of Meteorology |
| Excluded Goods Determination | *Therapeutic Goods (Excluded Goods) Determination 2018* |
| FDA | U.S. Food and Drug administration |
| GRASE | Generally Recognised as Safe and Effective |
| MoS | Margin of Safety |
| NOAEL | No Observed Adverse Effect Level |
| PoD | Point of Departure |
| Poisons Standard | Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) |
| SCCNFP | Scientific Committee on Cosmetic and Non-Food Products intended for Consumers |
| SCCS | Scientific Committee on Consumer Safety |
| SED | Systemic Exposure Dose |
| SPF | Sun Protection Factor |
| SSA | Skin Surface Area |
| Sunscreen Standard | Australian/New Zealand Standard Sunscreen products - Evaluation and classification AS/NZS 2604:2021 Amd 1:2022 |
| TGA | Therapeutic Goods Administration |
| The Act | *Therapeutic Goods Act 1989* |
| The Regulations | Therapeutic Goods Regulations 1990 |
| Therapeutic sunscreen | Primary and some secondary sunscreens regulated under the *Therapeutic Goods Act 1989* (see Attachment 1) |
| UF | Uncertainty Factor |
| UVR | Ultraviolet radiation |

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# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
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