Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Proposed adoption of the Australian/New Zealand Sunscreen Standard AS/NZS 2604:2021

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[1] to make sure they are safe, efficacious and high quality.

Standards Australia is the nation's peak non-government, not-for-profit standards organisation that develops internationally aligned Australian Standards (AS) in the national interest through a process of consensus. AS are voluntary documents that set out specifications, procedures and guidelines that aim to ensure products, services, and systems are safe, consistent, and reliable. On their own, AS are voluntary, there is no requirement for the public to comply with standards. However, the Australian and State and Territory governments can mandate a standard by referring to an AS or joint Australian/New Zealand Standards (AS/NZS) in their legislation[2].

Standards Australia publish an AS/NZS for sunscreens that details the procedures for testing the performance of all sunscreen products in Australia. It also provides required label statements for sunscreen products. The objective of the standard is to produce a means of testing and labelling sunscreens that will assist consumers to select a product which best suits their sun protection needs.

The AS/NZS for sunscreens is given legal effect for sunscreens regulated by the TGA by adoption in therapeutic goods legislation. The Australian/New Zealand Standard: Sunscreen products – Evaluation and classification (AS/NZS 2604:2012) (the **2012 Sunscreen Standard**) is currently adopted by the TGA by being referenced in the Therapeutic Goods Regulations 1990 (the **Regulations)** and in the Therapeutic Goods (Excluded Goods) Determination 2018 (the **Excluded Goods Order**).

In December 2022, Standards Australia published the Australian/New Zealand Standard: Sunscreen products – Evaluation and classification (AS/NZS 2604:2021) (amended) (the **2021 Sunscreen Standard**), which replaces the 2012 Sunscreen Standard. The 2021 Sunscreen Standard completes the transition of methods for determining broad spectrum, sun protection factor (SPF) and water resistance from local Australian and New Zealand test methods to globally written, agreed and published International Organization for Standardization (ISO) standards.

In order for compliance with the 2021 Sunscreen Standard to be a mandatory requirement for sunscreens regulated as therapeutic goods in Australia, it needs to be referenced in therapeutic goods legislation. Until such time as this occurs, sunscreens regulated as therapeutic goods will continue to be required, by law, to comply with the superseded 2012 Sunscreen Standard. That is, it will not be mandatory for therapeutic sunscreens to comply with the 2021 Sunscreen Standard and further, sunscreen manufacturers that do wish to comply with the latest standard will not be able to do so.

The TGA is proposing to adopt the 2021 Sunscreen Standard by removing references to the AS/NZS 2604:1998 (the **1998 Sunscreen Standard**[3]) and the 2012 Sunscreen Standard and replacing these with references to the 2021 Sunscreen Standard in the following therapeutic goods legislation:

- Item 7 of Schedule 4 to the Regulations
- Items 14 and 15 of Schedule 1 to the Excluded Goods Order
- Items 5 and 10 of Schedule 2 to the Excluded Goods Order

[1] Not all sunscreens are regulated by the TGA – refer to Regulation of sunscreens in this document.

[2] www.standards.org.au/about/what-we-do

[3] The 1998 Sunscreen Standard is referenced in the Excluded Goods Order as part of the transitional arrangements when the 2012 Sunscreen Standard was adopted.

The main changes in the 2021 Sunscreen Standard compared to the 2012 Sunscreen Standard are:

- Adoption of the following ISO Standards:
    - **ISO 24444:2019, Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF).** This standard supersedes **ISO 24444:2010** and includes three new reference standard sunscreens which will assist in increasing the accuracy of a lab determining an SPF.
    - **ISO Standard 24443:2021- Determination of sunscreen UVA photoprotection in vitro** This standard supersedes **ISO 24443:2012** and introduces testing methodology with greater analytical rigour.
    - **ISO 16217:2020, Cosmetics — Water immersion procedure for the determination of water resistance**. This is a new standard, but the process used was previously described in **ISO 24444.:2010.** Australia retains a 4hr water test period and continues to determine the SPF for labelling based on the SPF value after immersion.

Appendix 1 provides a detailed description of the changes in testing the 2021 Sunscreen Standard compared to the 2012 Sunscreen Standard.

- A new flow chart to assist sponsors (product owners) determine what part of the standard is applicable to primary or secondary sunscreens.
- Introduction of labelling instructions for the application of aerosol and spray pump pack sunscreens that provide consumers advice on the amount of sunscreen to apply for UVR protection and advises against spraying on the face or in windy conditions.

The key benefits of adopting the 2021 Sunscreen Standard include:

- Australian therapeutic sunscreens will be required to comply with the latest ISO standards for testing and therefore be in alignment with the requirements of international jurisdictions, which will increase the international reputation of the Australian sunscreen industry.
- With one of the highest rates of skin cancer in the world, the adoption of globally written, agreed and published ISO standards for determining SPF, broad spectrum and water resistance will give increased confidence to consumers using sunscreens to protect their skin from UVR.
- The new label instructions advising the correct application of aerosol and spray pump pack sunscreens will help reduce potential adverse events such as sunburn and product inhalation.

The costs to the sunscreen industry of adopting the 2021 Sunscreen Standard may include:

- increased cost for new testing requirements
- product reformulation and relabelling where required (noting that some existing formulations of currently approved sunscreens may meet the 2021 Sunscreen Standard and not require reformulation)
- new labelling for aerosol products
- potential redirection or ‘writing-off’ of existing stock.

As of October 2023, there were 839 sunscreens and 78 aerosol sunscreens included in the Australian Register of Therapeutic Goods (ARTG). The determination of regulatory cost is provided in Section 4 of this document.

This Impact Analysis considers 3 options for adoption of the 2021 Sunscreen Standard:

Option 1: Status Quo: All therapeutic sunscreens will continue to be required to comply with the 2012 Sunscreen Standard.

Option 2: Adoption of the 2021 Sunscreen Standard, with the following applying upon commencement:

- All new sunscreen products included in the ARTG will have to comply with the 2021 Sunscreen Standard.
- A 1-year transition for existing aerosol and spray pump pack sunscreens included in the ARTG to comply with labelling requirements.
- A 3-year transition where existing sunscreens included in the ARTG (aerosol and non-aerosol) can comply with the testing requirements of either the 2012 Sunscreen Standard or the 2021 Sunscreen Standard. At the end of the 3-year transition, all products included in the ARTG will be required to comply with the 2021 Sunscreen Standard.

Option 3: Adoption of the 2021 Sunscreen Standard, with the following applying upon commencement:

- All new sunscreen products included in the ARTG will have to comply with the 2021 Sunscreen Standard.
- A 1-year transition for existing aerosols and spray pump packs included in the ARTG to be compliant with the new labelling requirements.
- 5-year transition where existing sunscreens included in the ARTG (aerosol and non-aerosol) can comply with the testing requirements of either the 2012 Sunscreen Standard or the 2021 Sunscreen Standard. At the end of the 5-year transition, all products included in the ARTG will be required to comply with the 2021 Sunscreen Standard.

The TGA considers Option 3 is the preferred option as it will incur the lowest regulatory burden for industry in relation to compliance with testing requirements, while still addressing the safety concerns associated with aerosol products.

The adoption of the 2021 Sunscreen Standard into therapeutic goods legislation will be the decision of the Minister of Health and Aged Care, as informed by this IA. It is anticipated, if Ministerial approved is received, that the 2021 Sunscreen Standard could be adopted in mid-2024.

Background

Skin cancer rates in Australia

Populations that live in areas with intense ambient ultraviolet radiation (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 2 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, primarily caused by excessive UVR. 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)[4].

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[5] 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.

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)[6].

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)[7].

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

[4] www.ncbi.nlm.nih.gov/pmc/articles/PMC9858120

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

[6] https://www.dermcoll.edu.au/wp-content/uploads/2023/09/ACD-Statement-Impact-of-skin-cancer-in-Australia-August-2023.pdf

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

spent more of their lives in times when there was less skin cancer awareness (Australian Institute of Health and Welfare, 2023)[8].

In relation to mortality rates, data from the Australian Bureau of Statistics[9] shows 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)[10].

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)[11].

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)[12]. 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)[13].

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[14].

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

9 https://www.abs.gov.au/statistics/people/population/deaths-australia/2022

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

11 https://www.dermcoll.edu.au/wp-content/uploads/2023/09/ACD-Statement-Impact-of-skin-cancer-in-Australia-August-2023.pdf

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

13 https://www.dermcoll.edu.au/wp-content/uploads/2023/09/ACD-Statement-Impact-of-skin-cancer-in-Australia-August-2023.pdf

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

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[15].
- UVB (290–320 nm)[16] - most UVB is absorbed by the atmosphere, UVB comprises 5% of the solar UVR reaching the earth's surface.
- UVA 320–400 nm[17] - UVA is not filtered significantly by the atmosphere The majority of solar UVR reaching the earth's surface (approximately 95%) is UVA[18].

Exposure to UVR via sun exposure is estimated to cause around 95% of melanoma cases in Australia (Cancer Australia)[19]. Both UVA and UVB can cause 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)[20].

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 (2021 Sunscreen Standard).

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 using sunscreen.

There is a long history of health campaigns aimed at reducing skin cancer in Australia. The Australian Cancer Council 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. The Australian Cancer Council 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 radiation. 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)[21].

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

[16] The International Organisation for Standardisation (ISO) standard test methods

[17] The International Organisation for Standardisation (ISO) standard test methods

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

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

[20] https://www.sciencedirect.com/science/article/pii/S0165993622002072

[21] https://www.sciencedirect.com/science/article/pii/S0165993622002072

The use of sunscreens by Australian consumers

Many Australian consumers use sunscreen daily. Daily use of sunscreen has been proven to be effective in reducing the incidence of skin cancers and protecting humans from premature skin aging (Green *et al*, 2011)[22].

In a consensus statement for Australia and New Zealand, Whiteman *et al* (2019)[23] recommend that people living in Australia should apply sunscreen to the face/head/neck and all parts of the body not covered by clothing on all days when the UVR index is forecast to reach three or above, irrespective of their anticipated activities. For planned outdoors activities, sunscreen should be used alongside other sun protection measures. The authors conclude that increased use of sunscreen as part of the daily routine to reduce incidental sun exposure will lead to decreased incidence of skin cancer in the future.

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)[24] recommends that sunscreen be applied 20 minutes before going outside and reapplied every two hours. The average adult needs 35ml for one full body application, which is the equivalent of more than half a teaspoon to each arm and the face, and just over one teaspoon to each leg, the front of the body and the back.

A nationally representative survey conducted by the Cancer Council[25] 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 30 (40%)
- the most common sun protective behaviours among adults were wearing sunglasses (61%), wearing a hat (49%) using sunscreen with SPF15 or higher (42%).

A survey of Melbourne residents' sun-related attitudes and behaviour over 3 decades, between 1987 and 2017, shows a significant and sustained improvement sun protection behaviour. 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)[26].

Conversely, in a systematic scoping review exploring the use of sun-protection by outdoor sporting participants in Australasia, Morton *et al*., (2023) [27] concluded that adequate sun-protective behaviours are lacking despite 40 years of 'Slip Slop Slap' health promotion in Australasia.

Sunscreen testing

Sunscreens are available in a range of formulations, such as lotions, creams, gels and aerosol sprays. In Australia, regardless of the type, all therapeutic sunscreens need to comply with three labelling requirements – the Sun Protection Factor (SPF) test, the broad-spectrum test and the water resistance test:

- The 'SPF' indicates how effective the sunscreen is against sunburn and the numerical SPF value provides the user with a direct measure of the sunscreen efficacy.
- The 'broad spectrum' label implies that the sunscreen protects the skin from UVB and UVA radiation. Sunscreens with a 'broad spectrum' label offer higher protection.

[22] https://ascopubs.org/doi/10.1200/JCO.2010.28.7078

[23] www.researchgate.net/publication/330639950_When_to_apply_sunscreen_a_consensus_statement_for_Australia_and_New_Zealand

[24] https://www.arpansa.gov.au/understanding-radiation/radiation-sources/more-radiation-sources/sun-protection-sunscreen

[25] Trends in sun protection behaviours - Skin Cancer Statistics and Issues

[26] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6782093/

[27] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9858120/pdf/curroncol-30-00033.pdf

- The ‘water resistant’ label indicates that the sunscreen also remains effective in water (i.e., during swimming or after sweating) for a certain period of time, which is up to 4 hours in Australia (Zou *et al* 2022)[28].

There is currently only one laboratory in Australia that offers full sunscreen testing (SPF, broad spectrum and water resistance).There are multiple overseas laboratories that conduct testing to the harmonised ISO testing methods adopted by AS/NZS for sunscreens. Consistent with Good Manufacturing Principles for outsourcing activities, sponsors need to ensure that an overseas service provider can apply and interpret the requirements of the AS/NZS for sunscreens, in order to meet the sponsor certification requirements for the product to be supplied in the Australian market.

While the AS/NZS for sunscreens adopts harmonised ISO test methods for water resistance testing, it requires the determination of SPF post water immersion as the SPF value to be claimed on label and for sunscreen products with:

- at least 30 SPF or above, a maximum of 4-hour immersion period may be claimed.
- at least 15 SPF but less than SPF 30, a maximum of 2-hour immersion period may be claimed.
- at least 8 SPF but less than 15 SPF, a maximum of 40 minutes immersion period may be claimed.

In contrast, in Europe, the same ISO water resistant test methodology is used to support a label claim of ‘water resistant’ or ‘very water resistant’ after a period of 40 minutes or 80 minutes total immersion respectively, along with the pre-immersion determined SPF (provided that, the measured post immersion SPF is not less than 50% of the pre immersion SPF).

Regulation of sunscreens in Australia

In Australia, sunscreens are regulated as either cosmetics or therapeutic goods depending on a number of factors, such as their ingredients, health claims and claimed SPF.

The objective of regulation of sunscreens in Australia is to ensure their quality, safety and efficacy to protect consumers from the sun’s harmful UV radiation and reduce the incidence and tragic outcomes of skin cancer.

Sunscreens fall into two categories: ‘primary’ sunscreens and ‘secondary’ sunscreens. The Australian therapeutic goods legislation relies on the definition of primary and secondary sunscreens provided in the AS/NZS for sunscreens (as adopted by the TGA), as reproduced below:

- **Primary sunscreen product:** Product that is represented as being primarily to protect the skin from UV radiation.
- **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 for example:
  - Skin care
    - moisturising products for face, hand and body that are secondary sunscreen products for dermal application including anti-wrinkle, anti-ageing and skin-whitening products
    - sunbathing products that are secondary sunscreen products (e.g. oils, creams or gels) including products for tanning without sun, and “after-sun” skin care products.
  - Colour cosmetic products that are secondary sunscreen products and are either tinted base or foundation (make-up), or products intended for application to the lips (tinted or untinted).

Under the Act and supporting legislation, sunscreen products that are regulated as therapeutic goods by the TGA include:

- Primary sunscreens

[28] https://www.sciencedirect.com/science/article/pii/S0165993622002072

- 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 of 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 Excluded Goods Order (excerpt at Appendix 2). These include moisturisers with a SPF less than 15 and tinted foundations with a SPF up to 50+.

All sunscreens that are regulated as therapeutic goods by the TGA must be included in the 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 Regulations, excerpt below:

> 7 sunscreen preparations for dermal application, if:
> (a) the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:2012, as in force from time to time; and
> (b) the performance statements and markings on the label comply with that Standard; and
> (c) the sunscreen preparation only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act; and
> (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
> (e) the sunscreen preparation only has indications that are covered by a determination under paragraph 26BF(1)(a) of the Act; and
> (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

Listed 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. Listed sunscreens must comply with the standard for sunscreens adopted by the TGA. The 2012 Sunscreen Standard is currently adopted by the TGA, as referenced in the Regulations and in the Excluded Goods Determination.

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.

Recent changes to legislation

The Regulations previously included a provision for sunscreens with a SPF of less than 4 enabling these products to comply with the superseded 1998 Sunscreen Standard and be exempt from the requirement to be included in the ARTG. Products with such a low SPF do not provide adequate protection from the sun's UV radiation for users, particularly in Australia.

Due to concerns regarding the potential for shortage of sunscreens when the 2012 Sunscreen Standard was adopted by the TGA in 2012, transition arrangements were included in the Regulations to allow products with less than SPF 4 to continue to be exempt from inclusion in the ARTG. These products could be marketed in Australia based on compliance with the superseded 1998 Sunscreen Standard. These transition arrangements did not include an end date.

A TGA review of products marketed over the internet indicated there were only a very limited number of insect repellent/sunscreen combination products still relying on the transition provisions. The TGA contacted the owner of such products who advised that, with a reasonable transition period, the impact on their business would be minimal.

All respondents to a public consultation on the issue, conducted in April/May 2023, supported the TGA's proposal to remove exemption provisions for sunscreens with less than SPF 4 and did not identify any negative impacts for industry or consumers associated with the proposal.

The Office of Impact Analysis (OIA) considered that the proposal, to remove the exemption provisions for sunscreens with less than SPF 4, would not have more than minor impacts (OIA23-05254), as such, preparation of an Impact Analysis was not required. However, OIA advised that a broad

discussion of this measure should be included in the IA for the adoption of the 2021 Sunscreen Standard, as it is relevant to the regulatory context.

The OIA advised that the measures could go ahead independent of the adoption of 2021 Sunscreen Standard. As such, the Regulations were amended on 23 November 2023 to remove the outdated exemption provisions for sunscreens with less than SPF 4. Transition arrangements will enable sponsors who had stock in the market before this time to continue to supply those products for 3 years, from the date of effect. From 1 January 2027 all products with less than SPF 4 will need to comply with the sunscreen standard adopted by the TGA and will not be able to make any product label claims relating to sun screening.

The composition of the Australian sunscreen industry

Data in the Australian Register of Therapeutic Goods (ARTG) for sunscreens

As at 6 October 2023, there were:

- 917 therapeutic sunscreens included in the ARTG, with 196 sponsors.
- The majority of the sponsors (170) had less than 10 sunscreen products included in the ARTG.
- 76 manufacturers were listed for the 917 products. Most sponsors list multiple manufacturers for their products, so it is not possible to determine the actual products being manufactured by each manufacturer based on ARTG data.

Peak industry bodies representing the sunscreen industry

There are 2 peak industry bodies who represent the interests of the sunscreen industry:

- Accord is the national industry association representing manufacturers and suppliers of hygiene, personal care and specialty products, their raw material suppliers and service providers.
- Consumer Healthcare Products Australia (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.

Value of the Australian Sunscreen market

The IBISWorld's 2023 market analysis[29] 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[30].

[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

A key trend shaping the industry in recent years, has been the growing demand for skincare and sun-care 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[31].

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.
- 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[32].

The Australian/New Zealand standard for sunscreens

Standards Australia is the nation's peak non-government, not-for-profit standards organisation that develops internationally aligned AS and joint AS/NZS in the national interest through a process of consensus. Standards ensure the quality and consistency of products and services. Standards Australia state that there are six key benefits of standards:

1. **Boost confidence**: Businesses and consumers can feel confident that the products and services they develop and/or use are safe, reliable and fit-for-purpose.
2. **Enhance innovation**: New standards are developed to reflect the latest technologies, innovations and community needs.
3. **Give products a competitive edge**: In the eyes of consumers, products that comply with standards offer added value. International Standards give Australian exporters an instant competitive advantage when moving into overseas markets.
4. **Reduce barriers to international trade**: Regardless of where a product is made, standards mean it can be sold and used around the globe. Opening new doors to international trade, standards help Australian businesses compete globally and to a wider market.

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

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

5. **Reduce red tape**: Standards assist with harmonisation across Australia's laws and regulations.
6. **Help businesses thrive**: Standards make business transactions simpler and more efficient, assisting with risk mitigation and compliance.

Standards Australia publish an AS/NZS for sunscreens that details the procedures for testing the performance of all sunscreen products. It also provides required label statements for sunscreen products. The objective of the AS/NZS standard for sunscreens is to produce a means of testing and labelling sunscreens that will assist consumers to select a product which best suits their skin protection needs.

The history of the AS/NZS for sunscreens is below:

- First issued at the request of the then Commonwealth Department of Health in 1983 as AS 2604:1983 with sunscreens allowed a maximum SPF of 15+.
- The second edition was issued in 1986 as AS 2604:1986 where the definitions of secondary sunscreens, broad spectrum and water resistance were added.
- The third edition was issued in 1993 as AS/NZS 2604:1993 and was a joint Australian and New Zealand Standard with tighter limits on water resistance.
- The fourth and fifth editions were issued in 1997 as AS/NZS 2604:1997, with sunscreens allowed a maximum SPF of 30+ and in 1998 as AS/NZS 2604:1998, with revised categories in line with SPF 30+.
- The sixth edition was issued in 2012 as AS/NZS 2604:2012 and raised the SPF maximum to SPF 50+ and introduced test method references to ISO 24443 for in vitro broad-spectrum measurement and ISO 24444 for in vivo SPF, aligning these methods with international practice.

The AS/NZS for sunscreens is given legal effect for sunscreens regulated by the TGA by adoption in therapeutic goods legislation. The 2012 Sunscreen Standard is currently adopted by the TGA by being referenced in the Regulations and in the Excluded Goods Order.

Changes in the 2021 Sunscreen Standard

In December 2022, Standards Australia published the Australian/New Zealand Standard: Sunscreen products – Evaluation and classification (AS/NZS 2604:2021) (amended) (the **2021 Sunscreen Standard**). This standard was prepared by the Joint Standards Australia/Standards New Zealand Committee CS-042, Sunscreen Agents and replaced the 2012 Sunscreen Standard. The 2021 Sunscreen Standard completes the transition of methods for determining broad spectrum, SPF and water resistance from local Australian and New Zealand test methods to globally written, agreed and published International ISO standards for all participating members to adopt.

The 2021 Sunscreen Standard incorporates ISO standards for determining broad spectrum, SPF and water resistance. It also includes label instructions for the safe use of aerosol and spray pump pack sunscreens. The latest revision included a thorough revision by health, government, and industry experts to align with technological updates and international guidance.

The development of the 2021 Sunscreen Standard reflects the evolving nature of sun protection technology and international regulatory frameworks. The 2021 Sunscreen Standard does not mandate that sunscreens products reaching Australian consumers radically change in any aspect. Rather, the 2021 Sunscreen Standard provides an improved foundation (over the existing 2012 standard) in both analytically determining the critical attributes of sunscreen efficacy and presenting these attributes to Australian consumer in a more accurate manner.

The major changes in the 2021 Sunscreen Standard are as follows:

a. This revision completes the transition of methods for determining broad spectrum, SPF and water resistance from local Australian and New Zealand test methods to globally written, agreed and published ISO standards for all participating members to adopt.

b. ISO 24443:2012, *Determination of sunscreen UVA photoprotection in vitro*, has been superseded by ISO 24443:2021 *Cosmetics — Determination of sunscreen UVA photoprotection in vitro.* The key changes are —

   i. the addition of a method for calculation of critical wavelength

   ii. the addition of new sunscreen standards for sunscreen determinations for higher performing broad spectrum products

   iii. changes to account for photo-stability of test products by exposing them to specific measured doses of ultraviolet (UV) radiation prior to testing.

c. ISO 24444:2010, *Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF),* has been superseded by ISO 24444:2019. The key change is to improve the reproducibility and reliability of this test method. Specific changes include —

   i. replacement of the Fitzpatrick Skin Type for volunteer selection by a colorimetric instrument measurement

   ii. the addition of three new standard sunscreens P5, P6 and P8 for use with sunscreen tests for SPF 25 above

   iii. photographic examples of erythema responses for grading of results. A sample questionnaire for test subjects is included, removing the need for Appendix E of AS/NZS 2604:2012.

d. The water immersion procedure for the determination of water resistance now follows ISO 16217:2020, *Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance*. Australia and New Zealand still retain the 4 h water resistance test period and claim and, continue to determine SPF after immersion as the SPF value to use for labelling SPFs.

e. The new and revised ISO standards include normative requirements for standardised formats for test and results reporting.

f. Clarification of the definition of the difference between Primary and Secondary Sunscreens. This document now advises taking into account the overall presentation and purpose of a sunscreen when assigning a sunscreen as a primary or secondary sunscreen.

g. Introduction of instructions for the recommended method of application of sunscreen aerosols and sunscreen spray pump packs to ensure even and generous dosing applied from the correct distance and under optimum conditions while avoiding inhalation.

h. Addition of Appendix D, to provide guidance for testing and labelling, including an ordered sequence of questions to help identify whether a sunscreen is a primary or secondary sunscreen.

Detailed changes of the 2021 Sunscreen Standard are available at Appendix 1.

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

The problem

The AS/NZS for sunscreens is given legal effect for sunscreens regulated by the TGA by adoption in therapeutic goods legislation. The superseded 2012 Sunscreen Standard is currently adopted by the TGA by being referenced in the Regulations and in the Excluded Goods Determination.

In order for compliance with the 2021 Sunscreen Standard to be a mandatory requirement for sunscreens regulated as therapeutic goods, it needs to be referenced in therapeutic goods legislation. Until such time as this occurs, sunscreens regulated as therapeutic goods in Australia will continue to be required, by law, to comply with the superseded 2012 Sunscreen Standard.

Why it is a problem?

Quality and efficacy of sunscreens

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, 2021)[33]. 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)[34]. As sunscreens are used to protect human skin from UVR damage, the efficacy of sunscreen products is an important public health issue (Zhou *et al*)[35].

The universally accepted methods of sunscreen SPF and water resistance testing are *in vivo* methods involving human subjects. Sunscreen testing can be highly subjective and there can be a degree of variability in the results. For example, the response to a test may differ from one individual to another within the same skin type. The interpretation of skin type or degree of erythema can also differ dramatically from one individual to another. Further, the erythemal response may differ between individuals of different ethnic groups even after accounting for the skin type. This may result in issues related to sunscreen effectiveness in some sub-populations that may be more sun sensitive (Zhou *et al*)[36].

Due to the difficulties with testing and variability in test results, consistency of test methods used across all sunscreens is critical to establish confidence in the stated SPF and UVR protection. In that way, the test responses would all be standardised against the same test methods, rather than compounding the variability of test results by testing to different methodologies.

Currently, sunscreens marketed in Australia are tested to unique requirements specific to Australia. Adopting the 2021 Sunscreen Standard would align the Australian testing requirements in relation to SPF, broad spectrum and water resistance with the ISO standards used by sunscreen products available internationally, which would allow for consistency and easier market access to products. Complying with ISO standards ensures that products, services and systems are safe, reliable and of good quality. Organisations are then able to demonstrate that they have met internationally recognised requirements in critical areas such as quality, and this can help build trust and confidence with consumers, suppliers, regulators and other stakeholders. Regulators can have confidence in ISO standards to help develop better regulation, knowing that they have a sound basis established by global experts (ISO)[37].

If Australian sunscreens do not comply with the 2021 Sunscreen Standard there will be inconsistencies in testing requirements between Australia and overseas, and it will be difficult to make direct comparison between products tested to these different requirements. In addition, consumers and overseas jurisdictions may have reduced confidence in Australian manufactured sunscreens if they are not tested to the internationally recognised standards.

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

[34] https://www.dermcoll.edu.au/wp-content/uploads/2023/09/ACD-Statement-Impact-of-skin-cancer-in-Australia-August-2023.pdf

[35] https://www.sciencedirect.com/science/article/pii/S0165993622002072#bib16

[36] Sunscreen testing: A critical perspective and future roadmap - ScienceDirect

[37] ISO - Benefits of ISO standards

Alignment with overseas jurisdictions

In relation to the adoption of ISO standards for sunscreens in other countries:

- ISO test methods have been adopted in the European Union (E.U.) and recognised by Cosmetics Europe. According to E.U. requirements, member countries must adopt the European Community Cosmetics Directive, which includes, by inference, the requirement to test sunscreens for their efficacy.
- In the United Kingdom (UK), sunscreens are covered under The Cosmetic Products (Safety) Regulations 2008.These regulations interpret the E.U. requirements and cover safety and performance requirements for these goods considered as cosmetics.
- Association of Southeast Asian Nations (ASEAN) regulations and other requirements are essentially aligned with the E.U. and include general requirements for cosmetics, good manufacturing practices (GMP), permitted actives and labelling. Information on member country requirements can be found at http://aseancosmetics.org/default/asean-cosmetics-directive/technical-documents

Adoption of the latest ISO standards (included in the 2021 Sunscreen Standard) aligns with the TGA's Business Plan to strengthen Australia's regulatory approach by aligning where possible with international standards. It will also help Australia to meet our commitment, as a full member of ISO, to adopt international standards and withdraw conflicting national standards. In addition, it will help Australia meet the relevant substantive provisions under Annex 3 of the World Trade Organization Technical Barriers to Trade.

Aerosol sunscreen safety concerns

In their response to a public TGA consultation (April/May 2023) on the proposed adoption of the 2021 Sunscreen Standard, the ARPANSA advised they consider that aerosol sunscreens are a particular safety issue because the SPF on the container is not achievable by consumers under normal use, resulting in many reports of sunburn. Testing in a laboratory does not represent real-world use and environmental conditions which include many confounding factors, such as:

- Sunscreens are typically used outdoors, especially for re-application. Application under light wind (10kph) and moderate wind (20kph), can result in the majority of the application missing the skin target compared to application when there is no wind.
- Product variation in propellent (27%-83%) results in a varying spray time being required (4 -14 seconds per limb) to achieve the stated SPF.
- The actual volume of active ingredients per can and per 10 second spray is unknown, as the propellent and carrier (unless ethanol) percentages are not stated on the label.

Henderson *et al*., 2022[38] state that research has shown that as much as 93% of the sunscreen can be lost in moderate (20 kph) winds, conditions which occur 67–87% of the time between 9am and 4pm during summer at Australia's most popular beaches. Even in light wind conditions (10 kph), occurring 95% of the time, more than one-third of the sunscreen can be lost.

Aerosol sunscreens are mixed with various propellants and are more diluted than an equivalent volume of sunscreen lotion or cream. This means more of an aerosol sunscreen is required to achieve the same coverage as lotion or cream sunscreens. Adults should apply 35 to 40 ml of sunscreen to the whole body in a single application to achieve adequate protection. The average can of aerosol sunscreen contains approximately 90 to 100 ml of sunscreen formulation, excluding the propellant. This means that approximately 1/3 of a can of aerosol is required for a single application to cover the whole body. Inadequate labelling instructions for correct use of aerosol sunscreens can lead to sunburn and more tragic outcomes (such as skin cancer).

[38] Henderson SI, King KL, Karipidis KK, Tinker RA, Green AC. Effectiveness, compliance and application of sunscreen for solar ultraviolet radiation protection in Australia. Public Health Res Pract. 2022;32(1):e3212205 - www.phrp.com.au/issues/march-2022-volume-32-issue-1/sunscreen-effectiveness-compliance-and-application

In addition to the risks of sunburn from using aerosol sunscreens incorrectly, there are significant concerns associated with accidental inhalation of these products. The potential risk of deep lung deposition, which occurs when particles in an aerosol reach the unciliated airways in the lung may be associated with serious adverse effects such as asthma, emphysema, bronchospasm and obstructive pulmonary disease (COPD). Particles that do not reach the deep lung may be associated with less harmful adverse events such as local irritation of the upper airway, coughing or sneezing.

The 2021 Sunscreen Standard introduces label instructions for the appropriate application of aerosol and spray pump pack sunscreens, stating that sunscreen aerosols and sunscreen spray pump packs should be labelled with the following statements or words to the same effect:

i. Hold the container 10 to 15 cm away from the body and apply liberally and evenly until the product looks and feels wet on the skin.

ii. Do not spray directly onto the face. Spray onto hands and then apply to the face.

iii. Do not apply the product in windy conditions.

iv. Use in a well-ventilated area and avoid inhalation.

Implementation of these labelling requirements, and consumers complying with these instructions, will represent an essential improvement in the safety of these products and should reduce the number of adverse events caused by inappropriate or inadequate administration of these products. However, of note, ARPANSA consider these measures will not be enough to address the problem, as it relies on consumers reading and following the instructions on the product label. The TGA will consider ARPANSA's concern in future messaging to consumers on the use of sunscreens.

Evidence about the magnitude of the problem and the costs of not doing anything

The people, businesses affected by the problem

Australian public

Exposure to UVR via sun exposure is estimated to cause around 95% of melanoma cases in Australia (Cancer Australia)[39]. 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 incidence of skin cancer.

Requiring Australian sunscreens to align with international testing methods for sunscreens will maintain and increase consumers' confidence in the quality and efficacy of Australian sunscreens and assist in consumers adopting sun protection behaviour.

Government

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[40]). 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)[41]. Sunscreen is an important part of skin cancer prevention and it is important that Australian consumers have confidence in the efficacy and quality of the sunscreens they use. A lack of confidence in sunscreens (due to Australian

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

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

[41] https://www.dermcoll.edu.au/wp-content/uploads/2023/09/ACD-Statement-Impact-of-skin-cancer-in-Australia-August-2023.pdf

sunscreens not being tested to internationally accepted standards) may result in reduced sun protection behaviour, an increase in skin cancer in the Australian population and increased pressure on the Australian healthcare system.

Investments in skin cancer prevention programs, which promote sunscreen use alongside other sun protection measures, bring strong returns on investment. Whiteman *et al* [42] 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 sunscreen regularly will likely reduce future health care spending, patient medical expenses and other societal costs. As such, having high quality sunscreens that are compliant with internationally recognised ISO testing standards are essential to recognising the health benefit of sunscreens and future health cost savings.

Adverse events to aerosol products

The TGA has received a number of adverse event reports relating to aerosol sunscreens. A search of the Database of Adverse Events Notifications (DAEN)[43] was conducted on 9 October 2023, using the following methodology:

- A 5-year date range was selected: 25 September 2018 to 25 September 2023.
- The search term used was ‘sunscreen’ which returned 47 products. All products with ‘spray’ in their name were then manually selected from the list, resulting in 9 sunscreens. Limitations with this search include:
  - potential for human error due to the manual selection of aerosol sunscreens
  - some products may not include aerosol/spray in the product name and would be missed
  - it is limited by the number of adverse events entered into the database.

There were 18 reported cases (to the 9 aerosol sunscreens), of which there were 14 cases where there was a single suspected medicine. The 18 reported cases have been broken down by age as below:

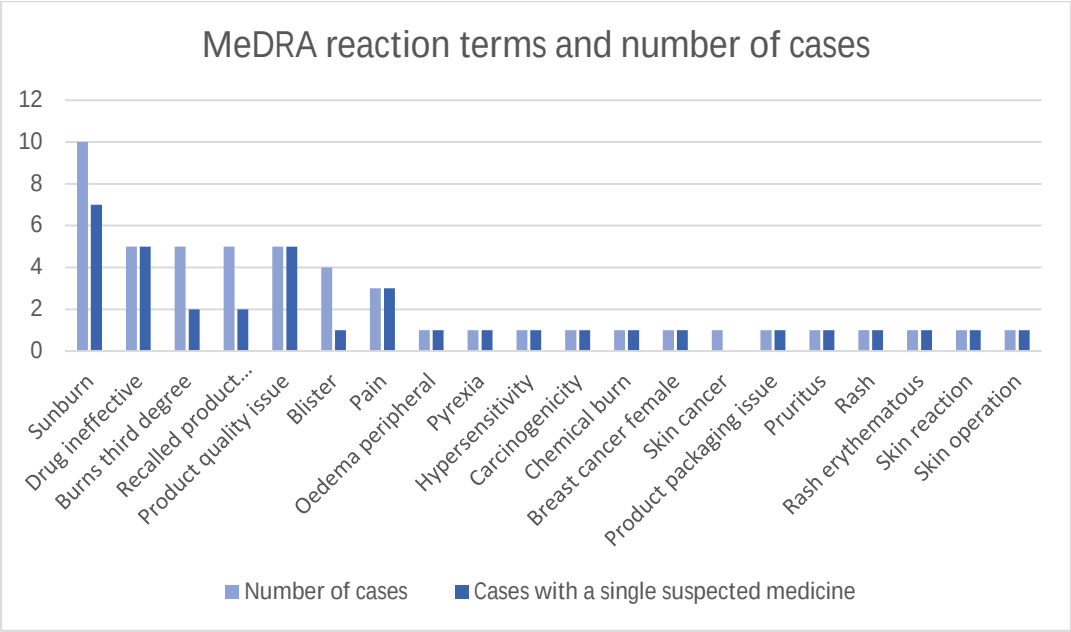
- 5 years = 1
- 5-11 years = 3
- 12-17 years = 1
- 18-64 years = 2
- Unknown = 11

The chart below includes the MedDRA reaction terms, and the number of cases associated with them. Note that each case may have more than one reaction.

[42] www.researchgate.net/publication/330639950_When_to_apply_sunscreen_a_consensus_statement_for_Australia_and_New_Zealand

[43] https://daen.tga.gov.au/medicines-search/

Chart 1: MedDRA reaction terms and the number of cases of adverse events to sunscreens



From Chart 1, it can be seen that of the cases linked to a single medicine, there were 13 reactions related to sunburn (’sunburn’, ‘drug ineffective’, ‘burns third degree’).

In addition to the concern of sunburn associated with aerosols, there is also the risk of adverse events related to inhalation, such as chronic lung conditions, which may take some time to develop.

Requiring aerosol products to include instructions on the proper use of aerosol sunscreens (as included in the 2021 Sunscreen Standard) will inform consumers and help reduce the incidence of adverse events.

Sunscreen industry

If the 2021 Sunscreen Standard is not adopted now and a decision is made to adopt it at a later date, there will be more sunscreens in the market and the cost of transition for industry will be significantly greater.

In addition, if the 2021 Sunscreen Standard is not adopted, the Australian sunscreen industry may face challenges in the future as less laboratories test to the Australian standards and move towards the internationally accepted ISO standards. Also, the international and consumer confidence in Australian made sunscreens may diminish, which will be a marketing disadvantage.

Current government measures

There is no requirement for sunscreens regulated as therapeutic goods to comply with Australian Standards unless they are referenced in therapeutic goods legislation. There are no other Government measures being undertaken to encourage compliance with the 2021 Sunscreen Standard.

Available data and plan to close any gaps that need to be addressed as part of the Impact Analysis process.

The costs to the sunscreen industry include increased cost for new testing requirements, product reformulation where required, new labelling for aerosol products and potential write-off of existing stock. The estimated cost of transitioning to the new standard is discussed in Section 4 of this document for the determination of regulatory cost.

There were gaps in the data provided by industry in relation to costs, including but not limited to, inadvertently missed costs, costs unable to be quantified and costs being aggregated into groups rather than a breakdown per steps in the manufacturing process (i.e. stability assessment vs SPF testing). These data gaps, assumptions and the concessions made are discussed in Section 4.

2. What are the objectives, why is government intervention needed to achieve them, and how will success be measured?

The primary objective of regulation of therapeutic sunscreens in Australia as therapeutic goods by the TGA is to ensure their quality, safety and efficacy with a view to protecting consumers from the sun's harmful UV radiation and reducing the incidence and tragic outcomes of skin cancer.

The primary objective of adoption of the 2021 Sunscreen Standard is to ensure consistency with testing and labelling instructions, domestically and internationally, which go together with better health outcomes for Australians. In that, consumers would have confidence in the products that they are using, which leads to better compliance and adverse events to aerosol and spray pump-pack sunscreens will be reduced through correct application of these products.

Successful adoption would see all therapeutic sunscreens compliant with the testing and labelling instructions of the 2021 Sunscreen Standard and a decrease in the incidence and mortality rates for skin cancer in Australia.

Government intervention is required to adopt the 2021 Sunscreen Standard into the Regulations and give it legal underpinning. All medicines, and therapeutic goods in general, must comply with certain standards before they can be included in the ARTG. In order for compliance with the 2021 Sunscreen Standard to be a mandatory requirement for sunscreens regulated as therapeutic goods in Australia, it needs to be referenced in therapeutic goods legislation. Until such time as this occurs, sunscreens regulated as therapeutic goods will continue to be required, by law, to comply with the superseded 2012 Sunscreen Standard.

That is, it will not be mandatory for therapeutic sunscreens to comply with the 2021 Sunscreen Standard and further, sunscreen manufacturers that do wish to comply with the 2021 Sunscreen Standard will not legally be able to do so. Over time, requiring Australian sunscreen sponsors to comply with unique Australian testing requirements will become increasingly difficult as testing laboratories move to testing to ISO standards.

Further, there are safety concerns in relation to adverse events for aerosol sunscreens due to incorrect application and potential inhalation. The 2021 Sunscreen Standard includes important label statements relating to the correct usage of aerosol sunscreens. If the 2021 Sunscreen Standard is adopted by the TGA, these label statements will be mandatory for therapeutic sunscreens.

An alternative government action that could be undertaken is the removal of the requirement to comply with the 2012 Sunscreen Standard from the therapeutic goods legislation and allow the industry to self-regulate the testing requirements for sunscreens. However, as testing requirements will not be mandatory, self-regulation by industry may result in sponsors using different testing methodologies which may result in increasing disparity of test results and reduced consumer confidence in the claimed SPF factor. A TGA consultation on sunscreens (April/May 2023) indicated that there is broad support from consumers, health professionals and organisations for sunscreen to be continued to be regulated by the TGA due to the importance of sunscreens to Australian consumers.

3. What policy options are you considering?

Option 1 – Status Quo

Do not adopt the 2021 Sunscreen Standard and instead allow sunscreens to continue to comply with the 2012 Sunscreen Standard. Sunscreens available in Australia will continue to comply with the unique Australian requirements and not be required to comply with the latest ISO standards.

Under Option 1, Australia would not meet our commitment as a full member of ISO to adopt international standards and withdraw conflicting national standards. Australia will also not meet the relevant substantive provisions under Annex 3 of the World Trade Organization (WTO) Technical Barriers to Trade.

In addition, TGA will not meet the health policy objective is to ensure the quality, safety and efficacy of sunscreens with a view to protecting consumers from the sun's harmful UVR and reducing the incidence and tragic outcomes of skin cancer.

Option 2 – Adoption of the 2021 Sunscreen Standard, with a 1-year transition for labelling and 3-year transition for testing

Option 2 will require all new sunscreen products included in the ARTG to immediately comply with the 2021 Sunscreen Standard from the date of commencement. The following transition requirements would apply to existing sunscreen products included in the ARTG prior to commencement:

- 1-year for existing aerosols and spray pump packs to comply with the new labelling requirements.
- 3-years where existing sunscreens (aerosol and non-aerosol) can comply with the testing requirements of either the 2012 Sunscreen Standard or the 2021 Sunscreen Standard. At the end of the 3-year transition, all products included in the ARTG will be required to comply with the testing requirements the 2021 Sunscreen Standard.

Sunscreens are typically designed to remain at their original strength for protecting consumers from the sun for up to three years[44]. With this in mind, a 3-year transition period aligns with the average turnover and shelf-life of products. A 3-year transition period allows manufacturers and sponsors a reasonable transition time to manage their product range, such as, stock levels, product reformulation and time to comply with testing requirements.

Under Option 2, Australia will meet our commitment as a full member of ISO to adopt international standards and withdraw conflicting national standards. Australia will also meet the relevant substantive provisions under Annex 3 of the WTO Technical Barriers to Trade.

In addition, TGA will meet the health policy objective is to ensure the quality, safety and efficacy of sunscreens with a view to protecting consumers from the sun's harmful UVR and reducing the incidence and tragic outcomes of skin cancer.

[44] Does Sunscreen Go Bad? | Expiry Dates Explained – Canstar Blue

Option 3 – Adoption of the 2021 Sunscreen Standard, with a 1-year transition for labelling and a 5-year transition for testing

Option 3 will require all new sunscreen products included in the ARTG to immediately comply with the 2021 Sunscreen Standard from the date of commencement. The following transition requirements would apply to existing sunscreen products included in the ARTG and released for supply prior to commencement:

- 1-year for existing aerosols and spray pump packs to comply with the new labelling requirements.
- 5-year transition where existing sunscreens (aerosol and non-aerosol) can comply with the testing requirements of either the 2012 Sunscreen Standard or the 2021 Sunscreen Standard. At the end of the 5-year transition, all products included in the ARTG will be required to comply with the testing requirements of the 2021 Sunscreen Standard.

A 5-year transition period is proposed because a number of industry submissions to the April/May 2023 sunscreen consultation sought a longer transition period, as they stated a shorter transition period of less than 5 years would cause testing and supply pressures and potential shortage of sunscreens in the peak sunscreen season. Further, there is only one testing laboratory in Australia that that offers full sunscreen testing, there will be high demand for the services of this laboratory, putting additional pressure on sponsors to achieve testing within a short time frame.

Under Option 3, Australia will meet our commitment as a full member of ISO to adopt international standards and withdraw conflicting national standards. Australia will also meet the relevant substantive provisions under Annex 3 of the WTO Technical Barriers to Trade.

In addition, TGA will meet the health policy objective is to ensure the quality, safety and efficacy of sunscreens with a view to protecting consumers from the sun's harmful UVR and reducing the incidence and tragic outcomes of skin cancer.

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

Consideration of industry regulatory costs

The calculations to determine the regulatory costing for industry are provided at Appendix 3. Costings are based on data provided 'in-confidence' to the TGA by sunscreen sponsors, industry representatives and sunscreen testing laboratories.

As at 6 October 2023, there were 917 therapeutic sunscreens included in the ARTG, with 196 sponsors. The majority of the sponsors (170) have less than 10 sunscreen products included in the ARTG. There were 76 manufacturers listed for the 917 products. Most sponsors list multiple manufacturers for their products, so it is not possible to determine the actual products being manufactured by each manufacturer based on ARTG data.

Table 2 provides the estimated worst-case scenario for industry to transition to the 2021 Sunscreen Standard and has been used as the data source for establishing the regulatory burden of Options 2 and 3. Note that the costing relates to actual costs to test to the requirements of the 2021 Sunscreen Standard and not additional costs. A direct cost comparison between the 2012 Sunscreen Standard and 2021 Sunscreen Standard was unable to be ascertained due to a number of factors affecting pricing structure including, inflation and routine yearly price changes.

Table 2: Industry costs to comply with 2021 Sunscreen Standard per product

Industry costs of transition per product		
Cost of 2021 Sunscreen Standard testing per product		
ISO 24444:2019		$5,287
ISO 24443:2021		$765
ISO 16217:2020		$8,250
TOTAL testing costs per product		**$14,302**
TOTAL testing costs averaged over 10 years per product		**$1,430.20**
Other potential costs of transition per product		
Costs	**Comment**	**Cost per product**
Cost of reformulation	May not be required where current formulation is compliant with the 2021 Sunscreen Standard.	$64,500
Cost of new labels and/or promotional materials	May be required for aerosol sunscreen products that do not have label advisory statements.	$8,500
Costs of write-off of labels and product	May not be required if sponsors have enough transition period to manage their existing stock.	$40,000
TOTAL other potential costs per product		**$113,000**
TOTAL other potential costs averaged over 10 years per product		**$11,300**

Table 2 assumes that all sunscreen sponsors will need to reformulate their sunscreen, develop new labels, develop new promotional material and write off product. In reality, this is not likely to be the case. Many products may already meet the requirements of the 2021 sunscreen standard and will not require reformulation or new labelling. In addition, the sunscreen and other skincare product manufacturing is characterised by a consistent stream of product launches (IBISWorld 2023), so it is likely that sponsors would consider reformulation and new advertising promotional materials as part of their usual business strategy. Further, it is unlikely that sponsors will write off stock and labels, as they will have strategies in place to run out stock, including discounting the price of stock, donating or exporting stock that meets the requirements of other countries. Therefore, the cost of transitioning a product to the 2021 Sunscreen Standard is likely to be far less than the figure provided in Table 2.

The costs of transitioning to the 2021 Sunscreen Standard may also be offset by the expected growth of the Australian sunscreen industry. The IBISWorld's 2023 market analysis[45] 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

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

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), 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.

Consideration of costs for retailers and consumers

It is difficult to quantify what costs may be incurred by retailers and potentially passed on to consumers as there are too many unknowns due to limitations on available data and several assumptions requiring to be made. These limitations are discussed below.

Limitations to determining costs for retailers

Industry representatives have advised the TGA that, typically, costs for developing and testing sunscreens would already be captured in the existing recommended retail prices. Where there are increased costs, manufacturers may not pass these costs on, or if they do, may pass the costs on gradually (e.g. quarterly or annually increases). However, the new testing methods contained in the 2021 Sunscreen Standard may increase the cost to the manufacture of sunscreens. For example:

- Sunscreens may require increased levels of actives or different combinations of actives to achieve the required SPF and broad-spectrum outcome.
- Newer actives may be subject to a patent, and the cost of these will remain higher until they come off patent (and other manufacturers can start producing them), resulting in higher manufacturing costs.

Conversely, other manufacturers may have already transitioned to using newer actives and the cost increases may have already occurred.

In relation to retail sales, IBISWorld (2023) provides the following are the most common retail markets for skin care products, in order of revenue:

- Online channels
- Pharmacies, including large chains such as Chemist Warehouse
- Grocery channels, such as Woolworths and Coles
- Department and specialty stores

IBISWorld (2023) states that online retail sales for the overall cosmetic industry have surged in recent years and top the retail market. As online sales continue to grow strongly, skincare manufacturers are launching new e-commerce platforms that sell directly to consumers. The next biggest retail market is large chain pharmacies and then grocery channels. As these outlets have high buying power as they buy products in bulk, there may not be a noticeable increase in price due to increased testing requirements.

Given the above, it is difficult to determine the costs that may be incurred by retailers and as such, these costs are not considered in the determination of the net benefit for Options 2 and 3.

Limitations to determining costs for consumers

If additional costs occur for retailers, some retailers may pass these on to consumers, or conversely, to remain competitive in the market they may decide not to pass on these additional costs.

It is difficult to determine what the current average cost of a sunscreen is for consumers, due to factors such as consumer choice of different pack sizes, difference in price ranges and premium brand pricing.

It is also difficult to determine the average use of sunscreens by consumers due to a large variety in lifestyles and variations of sunscreen application e.g. some consumers may not use sunscreen every

day and may only use sunscreen sparingly as they choose other sun protection behaviours. Conversely, other consumers may use sunscreen every day over large areas of their body, particularly people who work outside or undertake outdoor leisure activities. These varied lifestyles could mean one consumer uses a bottle of sunscreen over 3 years, while another consumer may go through multiple bottles of sunscreen each summer.

Another variable is the recommended quantity of sunscreen to use varies depending on the type of product e.g. aerosol compared to lotion. This adds to the difficulty of calculating an average usage as it is not known what proportion of the population use different formulations.

Investigation of online calculators designed to determine sunscreen usage yield large variability of results, which highlights the difficulty in determining an acceptable model for sunscreen usage.

As there are too many variables, it is not possible to determine the current average cost of sunscreens for consumers to then determine what additional costs may occur if manufacturers and retailers choose to pass costs on. As such, the costs to consumers of the adoption of the 2021 Sunscreen Standard have not been considered in the determination of the net benefit for Options 2 and 3.

Consideration of environmental costs

Another issue to consider is environmental costs of disposal of sunscreens, if destruction of stock is required due to the adoption of the 2021 Sunscreen Standard.

Destruction of such stock is not inevitable. The TGA understand that sponsors would prefer to avoid destruction of “perfectly good” stock. Sunscreens compliant with the 2012 Sunscreen Standard have been manufactured to high standard and continue to hold the protective benefits of a sunscreen. There are potentially alternate avenues through which such sunscreen stocks (compliant with the 2012 Sunscreen Standard) may have commercial value and continue to be beneficial; including export to world regions where regulation is absent, sunscreens are not readily available or where demand outstrips supply. Further, some non-complaint stocks may be suitable as a base component of sunscreen reformulation.

Where disposal is required then typically this needs to be by incineration rather than landfill, as this avoids the risk of the product being inappropriately recovered. However, this is not appropriate for aerosol sunscreens, which would be required to be disposed in landfill.

Industry peak bodies have advised that disposing of sunscreen stock due to not complying with the 2021 Sunscreen Standard would only become significant if industry is not allowed, as part of transition arrangements, to sell through remaining product. Sponsors have an obligation to buy back excess stock at the end of the summer season while allowing sufficient supply to cover winter usage. This is managed by tracking sales against forecast sales and adjusting production volumes to minimise stock return. As such, if sponsors are allowed to sell through stock released to comply with the 2012 Sunscreen Standard, then return of stock at the end of the summer season would not differ from current practices.

Taking the above into consideration, it is not anticipated that adopting the 2021 Sunscreen Standard will have any additional environmental impacts and hence these are not considered in the net costings for Options 2 and 3.

Option 1 Estimated net benefit

Benefits of Option 1

Benefits of Option 1 for industry

- Maintaining the status quo will have no additional costs to business (manufacturers or retailers) (Table 3).
- Sponsors will not have to reformulate their products or change their promotional material.

Table 3: Average annual regulatory costs for Option 1

Average annual regulatory costs			
Costs ($)	**Business ($)**	**Individuals ($)**	**Total change in costs ($)**
Option 1	Nil	Nil	Nil

Benefits of Option 1 for consumers

- The products consumers are familiar with will remain on the market.
- There will be no reduction in sunscreens available in the market.
- There will be no increase in product price caused by costs of transitioning to the 2021 Sunscreen Standard.

Benefits of Option 1 for government

- There will be no reduction in sunscreens available in the market.

Disadvantages of Option 1

Disadvantages of Option 1 for industry

- Australian sunscreens will not be in alignment with international testing standards, which may dimmish the Australian sunscreen industry's reputation internationally.
- Sunscreen manufacturers will not be able to comply with the 2021 Sunscreen Standard, even if they are a position and willing to do so.
- Over time, sunscreen testing laboratories may stop offering the testing stipulated in the 2012 Sunscreen Standard, given that international markets do not use them, which will make it harder for Australian sponsors to get their sunscreens tested.
- If a decision is made to adopt the 2021 Sunscreen Standard at a later date, due to the increase of the sunscreen market over time, the regulatory cost to industry will be greater.

Disadvantages of Option 1 for consumers

- Safety concerns relating to consumers' inappropriate usage of aerosol sunscreens will not be addressed and adverse events to these products may increase.
- Consumers may have reduced confidence in sunscreens and adversely alter their sun protective behaviour.
- There may be a shortage of sunscreens as sunscreen manufacturers find it increasingly difficult to find testing laboratories that will continue testing to Australian standards rather than internationally accepted ISO standards.

Disadvantages of Option 1 for government

- Safety concerns relating to consumers' inappropriate usage of aerosol sunscreens will not be addressed and adverse events to these products may increase.
- Australia would not meet our commitment, as a full member of ISO[46] to adopt international standards and withdraw conflicting national standards. Australia will also not meet the relevant substantive provisions under Annex 3 of the World Trade Organization Technical Barriers to Trade.

[46] Iso membership manual

- Australian sunscreens will not be in alignment with international testing standards, which may dimmish the Australian sunscreen industry's reputation internationally and in turn, diminish the Governments reputation as a regulator of these products.
- Australian consumers may lose confidence in the efficacy of Australian sunscreens and alter their sun protective behaviour, resulting in an increase in skin cancer and increasing burden on the healthcare system.
- Potential loss of export sales, as Australia may not be able to export to some countries if Australian sunscreens do not comply with ISO standards.

Option 2 Estimated net benefit

Benefits of Option 2

Benefits of Option 2 for industry

- The 3-year transition period provides adequate transition arrangements for existing products and allow sponsors to manage their product range, stock levels, develop alternative product lines, transition labelling, promotional and advertising materials and sell-through of existing stock.
- Sunscreen manufacturers will be able to transition earlier to the 2021 Sunscreen Standard where they are in a position to do so.
- This option would ensure that there is little or no disruptions to the supply of sunscreen products as existing sunscreen products would have adequate time to transition to the new 2021 Sunscreen Standard.
- Less dollar value write-off of printed packaging or promotional material, due to having the ability to plan ahead.
- Potential increase in opportunities to export sunscreens as Australia would be complying with the lates ISO standards.

Benefits of Option 2 for consumers

- It will address safety concerns regarding the incorrect use of aerosol or spray pump pack sunscreens through new labelling requirements directing consumers on appropriate use.
- There will be little disruption to the supply of sunscreen products as existing sunscreen products would have adequate time to transition to the new 2021 Sunscreen Standard.
- There will be maintained or increased consumer confidence in the quality of Australian sunscreens and increased sun protection behaviour.

Benefits of Option 2 for Government

- Having high quality sunscreens that are compliant with internationally recognised ISO testing standards are essential to recognising the health benefit of sunscreens and future health cost savings.
- Australia will meet our commitment, as a full member of ISO[47], to adopt international standards and withdraw conflicting national standards. Australia will also meet the relevant substantive provisions under Annex 3 of the World Trade Organization Technical Barriers to Trade.

[47] Iso membership manual

Disadvantages of Option 2

Disadvantages of Option 2 for industry

- Option 2 provides a 1-year transition for aerosols to comply with labelling requirements, which will require sponsors of these products to update their labels and there may be a write-off of stock. In addition, the costs of transitioning will likely be a one-off cost at the end of transition.
- In their response to the April/May 2023 consultation, CHP Australia and Accord did not support the proposed 1-year transition timeframe for aerosol sunscreens if the transition ended in the peak of the sunscreen season. They requested the ending of transition to avoid the peak sun season (i.e. until July 2025).
- In consultation submissions, sunscreen sponsors, ACCORD and CHP Australia did not support a 3-year transition timeframe for testing of all sunscreens, due to testing costs, limited testing laboratories and supply pressures with the potential shortage of sunscreens in the peak sunscreen use season. Rather, they proposed a 5-year transition, which would reduce the burden on resources and allow the costs to be spread over a longer period. CHP Australia contended that while the 2021 Sunscreen Standard adopts new technical testing methodologies, there are no safety or quality concerns being addressed in the 2012 Sunscreen Standard. That is, compliance with the 2012 Sunscreen Standard will still guarantee safe and efficient sunscreen products, with no risk to consumers.
- Compliance with the 2021 Sunscreen Standard will involve testing, possible re-formulation and new labelling for existing products. The calculation of potential regulatory burden for industry Option 2 is provided in Table 4.

Table 4: Calculations to determine the regulatory burden of adopting Option 2

Type	Additional cost per product		No of products in ARTG	Total industry cost all products	Total industry cost all products over 10 years
Non-aerosol Sunscreens	Testing	$14,302	839	$99,674,878.00	$9,967,487.80
	Reformulation	$64,500			
	Write off stock	$40,000			
	Labelling	-			
	TOTAL	$118,802			
Aerosol sunscreens	Testing	$14,302	78	$6,809,556	$680,956
	Reformulation	$64,500			
	Write off stock	-			
	Labelling	$8,500			
	TOTAL	$87,302			
TOTAL cost aerosol and non-aerosol				**$106,484,434**	**$10,648,443**

Disadvantages of Option 2 for consumers

- For aerosol and spray pump pack sunscreens there is a risk that there will be products available to consumers with different usage instructions as new products would be compliant with the requirements of the 2021 Sunscreen Standard compared to existing products that have not transitioned, which may be a source of confusion.
- There may be additional costs incurred by retailers due to the costs of complying with the 2021 Sunscreen Standard—which could potentially be passed onto consumers.

Disadvantages of Option 2 for Government

- If sponsors are not able to comply with the 2021 Sunscreen Standard by the end of the 3-year transition period there may be a reduction in sunscreens in the Australian market.

Option 3 Net benefit costs

Benefits of Option 3

Benefits of Option 3 for industry

- 5-year transition arrangements for existing products will allow sponsors to manage their labelling, promotional and advertising materials and sell-through of existing stock, significantly reducing write-off costs. Less dollar value write-off of printed packaging or promotional material, due to having the ability to plan ahead.
- Sunscreen manufacturers will be able to transition earlier to the 2021 Sunscreen Standard where they are in a position to do so.
- This option would ensure that there are no disruptions to the supply of sunscreen products as existing sunscreen products would have adequate time to transition to the new 2021 Sunscreen Standard.
- A 5-year transition period will allow sponsors more time to get their sunscreens tested by the limited number of testing laboratories.
- Potential increase in opportunities to export sunscreens as Australia would be complying with the latest ISO standards.

Benefits of Option 3 for consumers

- It will address safety concerns regarding the incorrect use of aerosol or spray pump pack sunscreens through new labelling requirements directing consumers on appropriate use.
- There will be little disruption to the supply of sunscreen products as existing sunscreen products would have adequate time to transition to the new 2021 Sunscreen Standard.
- There will be maintained or increased consumer confidence in the quality of Australian sunscreens and increased sun protection behaviour.

Benefits of Option 3 for Government

- Having high quality sunscreens that are compliant with internationally recognised ISO testing standards is essential to recognising the health benefit of sunscreens and future health cost savings[48].
- Australia would meet our commitment as a full member of ISO[49] to adopt international standards and withdraw conflicting national standards. Australia will also meet the relevant substantive provisions under Annex 3 of the WTO Technical Barriers to Trade.

Disadvantages of Option 3

Disadvantages of Option 3 for industry

- Option 3 provides a 1-year transition for aerosols to comply with labelling requirements, which will require sponsors of these products to update their labels and there will likely be a write-off of stock. In addition, the costs of transitioning will likely be a one-off cost at the end of transition.

48 www.researchgate.net/publication/330639950_When_to_apply_sunscreen_a_consensus_statement_for_Australia_and_New_Zealand

49 Iso membership manual

- In their response to the April/May 2023 consultation, CHP Australia and Accord did not support the proposed 1-year transition timeframe for aerosol sunscreens if the transition ended in the peak of the sunscreen season. They requested the ending of transition to avoid the peak sun season (i.e. until July 2025).
- There will be costs to industry of complying with 2021 Sunscreen Standard. These are provided in Table 5.

Table 5: Calculations to determine the regulatory burden of adopting Option 3

Type	Additional cost per product		No of products in ARTG	Total industry cost all products	Total industry cost all products over 10 years
Non-aerosol Sunscreens	Testing	$14,302	839	$66,953,878	$6,695,387.80
	Reformulation	$64,500			
	Write off stock	$1,000			
	Labelling	-			
	TOTAL	$79,802			
Aerosol sunscreens	Testing	$14,302	78	$6,809,556	$680,956
	Reformulation	$64,500			
	Write off stock	-			
	Labelling	$8,500			
	TOTAL	$87,302			
TOTAL cost aerosol and non-aerosol				**$73,763,434**	**$7,376,343**

Disadvantages of Option 3 for consumers

- For aerosol and spray pump pack sunscreens there is a risk that there will be products available to consumers with different usage instructions as new products would be compliant with the requirements of the 2021 Sunscreen Standard compared to existing products that have not transitioned, which may be a source of confusion.
- There may be additional costs incurred by retailers due to the costs of complying with the 2021 Sunscreen Standard—which could potentially be passed onto consumers.

Disadvantages of Option 3 for Government

- Nil.

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

TGA consultation

In 2022 and 2023 the TGA conducted a targeted consultation with a number of industry groups to advise them of the TGA's intention to adopt the 2021 Sunscreen Standard. This included bilateral meetings with Accord Australasia and Consumer Healthcare Products Australia (CHP Australia), as well as the Complementary and OTC Medicines Regulatory and Technical Consultative Forum (ComTech).

In addition, TGA conducted a public consultation (from 24 April 2023 to 31 May 2023) on potential clarification and updates to the regulation of sunscreens, including the adoption of the 2021 Sunscreen Standard. A broad range of stakeholders provided submissions (19 in total) including: sponsors, manufacturers, regulatory affairs associates and consultants, industry groups, Government

agencies and organisations, consumers and consumer representative bodies, and a not-for-profit organisation.

All stakeholders were supportive of adopting the 2021 Sunscreen Standard as it would ensure alignment with international sunscreen testing methodology. The majority of respondents agreed that all new sunscreens should be required to comply with the 2021 Standard from adoption commencement date.

Transition period for compliance with new testing requirements

Industry requested a longer transition period than the 3-year period proposed in the consultation to comply with the new testing requirements. Sunscreen sponsors and industry representative bodies, Accord and CHP Australia, expressed concern with a 3-year transition timeframe due to testing and supply pressures and the potential shortage of sunscreens in the peak sunscreen use season. They advised that compliance with the 2021 Sunscreen Standard would involve costly testing, possible re-formulation and new labelling for existing products. Another respondent stated that there is only one lab in Australia that can test to the new 2021 Sunscreen Standard's requirements which puts additional pressure on sponsors to achieve testing.

CHP Australia stated that there were issues with the seasonality of sunscreens with product approvals required in April or May for the next summer season and supply of products commencing in September. In addition, CHP Australia advised that sponsors procuring materials for next summer's sunscreen stock production are finding that there is a shortage of sunscreen ingredients due to factors such as gas rationing in Europe due to the war in Ukraine. There is also a shortage of ingredients from the US, possibly due to dependence on starting materials from the EU. The impacts of gas rationing may continue to impact supply availability for some time.

CHP Australia also stated that this work is occurring at a time when the safety of currently approved sunscreen actives is under scrutiny with no outcome determined. This is a cause of further uncertainty for industry.

CHP Australia contend that while the 2021 Sunscreen Standard adopts new technical testing methodologies, there are no safety or quality concerns being addressed in the 2012 Sunscreen Standard. That is, compliance with the 2012 Sunscreen Standard will mean that Australian sunscreens continue to comply with unique Australian Standards for quality, until such time as the 2021 Sunscreen Standard is adopted. The TGA maintains that there will be inconsistencies between testing requirements and difficult to make direct comparison between products tested to different Australian and international requirements. However, the TGA agrees that the transition to the testing requirements to the 2021 Sunscreen Standard can be gradual to manage the regulatory costs to industry.

Option 3 (the TGA's proposed preferred option) proposes a 5-year transition to take into consideration industry feedback.

'Supply' vs 'release for supply'

Industry asked for clarification as to whether a 'new' product refers to when the product is 'supplied in the marketplace or the 'released for supply' by the manufacturer as the last step in the manufacturing process.

'Supply' (as defined in the Act) occurs when the product is released into the retail market, whereas 'release for supply' is:

- the last manufacturing step (licensable) within Australia and is mandatory for medicinal products manufactured according to principles of good manufacturing principles
- is performed through a legally valid signature of an authorised person who verifies that all production and quality control testing records of a batch comply with Chapters 2 and 3 of the Act.

The TGA has clarified in Options 2 and 3 that a 'new' product refers to a new listing in the ARTG on or after the commencement date of the adoption of the 2021 Sunscreen Standard. In relation to the end of the transition period for existing products (included in the ARTG prior to commencement date) all products will need to comply with the 2021 Sunscreen Standard on the first day following the end of

transition period. In relation to supply, all products released for supply from the first day after the end of the transition period will be required to comply with the 2021 Sunscreen Standard.

Transition period for aerosol sunscreens

Several sponsors did not oppose a shorter transition period for aerosol and spray pump pack sunscreens to comply with new labelling requirements provided that the effective transition date is defined as when the product is 'released for supply'.

CHP Australia and Accord did not support the proposed 1-year transition timeframe, due to the seasonality of the products. The timing of the commencement and end of the transition period would occur in the peak of the sunscreen season. They requested the ending of transition to avoid the peak sun season (i.e. until July 2025). At that timing, surplus sunscreen stock would have been withdrawn from the market from the previous season and the next season commencing in October, with pump spray and aerosol sunscreens able to run out the old label stock and start transitioning to the new labelled stock.

CHP Australia also advised that products imported from overseas would naturally have longer lead-times to implement label changes and have them on shelf, when compared with products manufactured locally, due to the sea freight timeframe component from the E.U. or US to Australia of 12+ weeks.

If the 2021 Sunscreen Standard is adopted, the commencement date is anticipated to be June 2024, which would align with industry's request for the commencement to be not in peak summer season.

ARPANSA, conversely, stated that aerosol sunscreens be removed from the market altogether due to potential adverse events due to incorrect administration and potential inhalation. While acknowledging ARPANSA's stance, the TGA considers that implementation of new label advisory statements for aerosol sunscreens will go some way to mitigating concerns in relation to incorrect usage of these products while still enabling consumers the choice to use these products. The efficacy of these measures will be reassessed post implementation.

6. What is the best option from those you have considered and how will it be implemented?

Preferred option

The TGA considers Option 3 is the preferred option as it will incur the lowest regulatory burden for industry in relation to compliance with testing requirements (see Table 6), while still addressing the safety concerns associated with aerosol products. In addition, there will be adequate time to manage existing stock (compliant with the 2012 Sunscreen Standard) to limit product disposal. Further, sunscreen sponsors will be able to comply with the new 2021 Sunscreen Standard as soon as they are in a position to do so which will ensure continuity of product in the marketplace.

Table 6: Average annual regulatory costs for the three proposed options

Average annual regulatory costs for all products over 10 years	
Costs ($)	**Business ($)**
Option 1	-
Option 2	$10,648,443
Option 3	$7,376,343

Under Option 3, Australia will meet our commitment as a full member of ISO to adopt international standards and withdraw conflicting national standards. Australia will also meet the relevant substantive provisions under Annex 3 of the WTO Technical Barriers to Trade.

In addition, TGA will meet the health policy objective to ensure the quality, safety and efficacy of sunscreens with a view to protecting consumers from the sun's harmful UV radiation and reducing the incidence and tragic outcomes of skin cancer.

Comparison of net benefits of options 1 and 2 compared to Option 3

Option 1, maintaining the *status quo*, would pose no additional cost for manufacturers, sponsors, retailers or consumers. However, this option would not address any of the objectives and reasons for adopting the 2021 Sunscreen Standard.

Like Option 3, Option 2 would meet the objectives of aligning with international standard for testing for SPF and water resistance after the transition period and address safety concerns regarding incorrect use of aerosol or spray pump pack sunscreens. However option 2 would incur more regulatory cost for industry, which may be passed on to retailers and consumers.

Implementation

Implementation plan for Option 3

The adoption of the Sunscreen Standard into therapeutic goods legislation will be a final decision of Government, as informed by this IA. It is anticipated that this could occur mid-2024.

At that timing, surplus sunscreen stock would have been withdrawn from the market from the previous season and the next season commencing in October, with pump spray and aerosol sunscreens able to run out the old label stock and start transitioning to the new labelled stock. Ending the transition period off peak summer season acknowledges industry's concern in relation to supply.

The stages of implementation are provided below:

- **February 2024**:
  - Seek Ministerial approval to adopt 2021 Sunscreen Standard.
  - inform stakeholders of proposed changes to adopt the 2021 Sunscreen Standard
  - commence legal drafting of legislation to adopt the 2021 Sunscreen Standard
- **April 2024**: submit regulatory amendments for approval of Executive Council.
- **June 2024**:
  - the 2021 Sunscreen Standard adopted into legislation
  - sponsor notification of adoption of 2021 Sunscreen Standard
  - messaging to sponsors of the transition arrangements for complying with the 2021 Sunscreen Standard.
- **March 2025**: stakeholder messaging via mass email mailout and social media messaging to highlight the end of the 1-year transition arrangements for aerosol labelling requirements
- **June 2025**: transition arrangements for aerosol labelling requirements ends.
- **March 2029**: stakeholder messaging via email and social media messaging to highlight the end of the 5-year transition arrangements to comply with the 2021 Sunscreen Standard, in June 2029.
- **June 2029**:
  - 5-year transition period ends.
  - update to legislation to remove references to the 2012 Sunscreen Standard.

Implementation risks

- Sponsors may withdraw products from the market if they cannot comply with the new Standard.

- With a 5-year transition, sponsors may leave their transition to new testing requirements until the very end of the transition period, which may result in a shortage of sunscreen products in the market.
- As there is only one laboratory that can fully test sunscreens in Australia, there is a risk that not all sunscreens will be able to be tested, where sponsors choose for their testing to be conducted in Australia.

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

TGA compliance activity

The TGA will monitor, through post market surveillance, the compliance of aerosol or spray pump pack sunscreen products with the new labelling requirements at the end of the transition period. This will be carried out as part of a compliance project where all listed aerosol or spray pump packs are selected and undergo a targeted post-market review of labelling. By **June 2025**, 100% of labels will be expected to comply and regulatory action will be taken if any products are found not to comply.

For testing requirements, a post-market compliance review will be taken on a selection of sunscreens included in the ARTG to determine if these good are compliant with the 2021 Sunscreen Standard at the end of the 5-year transition period. By **June 2029**, 100% of products will be expected to comply with the testing requirements and regulatory action will be taken if any products are found not to comply.

TGA monitoring of adverse events reports

The TGA will monitor the adverse events for aerosol products over a 10-year period from the adoption of the 2021 Sunscreen Standard in **June 2024**. A baseline figure before implementation will be determined to see how many adverse events were reported prior to adoption of the 2021 Sunscreen Standard. Yearly reports post-implementation will be used to determine if there has been a reduction in adverse event reports as a result of the improved labelling requirements for aerosol sunscreens. Success will be considered to be a reduction in adverse events associated with aerosol and other sunscreens.

Role of Industry

Therapeutic sunscreens will be expected to be fully compliant with the 2021 Sunscreen Standard at the end of the transition periods, **June 2025** and **June 2029**. Sponsors and manufacturers will be expected to plan the transition of their products to the 2021 Sunscreen Standard to minimise their costs, reduce stock write-off and ensure there is no shortage of sunscreens at the end of the transition period.

Role of industry peak bodies

The TGA will liaise with industry peak bodies over the 5-year transition period to seek feedback on the progress towards testing as per the 2021 Sunscreen Standard, the actual costs and any other unforeseen issues encountered. Peak bodies can provide an update to the TGA at the TGA's Industry forum (ComTech) which meets twice a year. Success will be considered to be all sunscreens to have transitioned at the end of the transition period, **June 2029**, with costs minimised as much as possible.

Role of consumers

Consumers will be expected to comply with new labelling instructions for aerosol sunscreens and report any adverse events associated with sunscreens to the TGA.

Role of professional organisations

The TGA will continue to liaise with ARPANSA to determine if the new labelling requirements for sunscreens have been effective in allaying their concerns for the use of aerosol sunscreens. If there are continued concerns in relation to the safety of aerosol sunscreens, further discussions on other solutions will occur.

The TGA will also monitor developments with other organisations, such as the Australian Sunscreen Council on matters relating to the Australian public and sunscreens.

Conclusions

The benefits of adopting the 2021 Sunscreen Standard include:

- Australian sunscreens will be required to comply with the latest ISO standards for testing and therefore be in alignment with the requirements of international jurisdictions.
- With one of the highest rates of skin cancer in the world, the adoption of globally written, agreed and published ISO standards for determining SPF and water resistance will give increased confidence to consumers when choosing sunscreens to best protect their skin from the sun.
- The new label instructions for the application of aerosol and spray pump pack sunscreens will advise consumers on the correct usage of these products which will help reduce potential adverse events such a sunburn and product inhalation.
- Australia would meet our commitment, as a full member of ISO[50], to adopt international standards and withdraw conflicting national standards. Australia will also not meet the relevant substantive provisions under Annex 3 of the World Trade Organization Technical Barriers to Trade.

Although adopting the 2021 Sunscreen Standard may have an increased regulatory impact for industry, sponsors should be able to manage this impact over the generous transition arrangements of the preferred option for implementation. In addition, with the current worth and predicted growth of the sunscreen market in Australia[51], industry should be able to absorb the costs.

[50] Iso membership manual

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

Key Terms/Glossary

Table 7: List of abbreviations used in this document

Document and terms	Abbreviation
Australian/New Zealand Standard Sunscreen products - Evaluation and classification AS/NZS 2604:1998	1998 Sunscreen Standard
Australian/New Zealand Standard Sunscreen products - Evaluation and classification AS/NZS 2604:2012	2012 Sunscreen Standard
Australian/New Zealand Standard Sunscreen products - Evaluation and classification AS/NZS 2604:2021 Amd 1:2022	2021 Sunscreen Standard
Australian Radiation Protection and Nuclear Safety Agency	ARPANSA
Australian Register of Therapeutic Goods	ARTG
Australian Regulatory Guidelines for Sunscreens	ARGS
Electronic Listing Facility	ELF
Standard for the Uniform Scheduling of Medicines and Poisons	Poisons Standard
Sun Protection Factor	SPF
Therapeutic Goods Act 1989	the Act
Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021	Advertising Code
Therapeutic Goods (Excluded Goods) Determination 2018	Excluded Goods Determination
Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021	Permissible Indications Determination
Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2023	Permissible Ingredients Determination
Therapeutic Goods Regulations 1990	the Regulations

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Appendix 1: Comparison of sunscreen standards

Table 8: 2021 Sunscreen Standard compared to 2012 Sunscreen Standard

2012 Sunscreen Standard	2021 Sunscreen Standard
ISO 24444:2010 cosmetic -Sun protection test methods-in vivo determination of the SPF.	ISO 24444:2019 cosmetic -Sun protection test methods-in vivo determination of the SPF
ISO 24443:2012 Determination of sunscreen UVA photoprotection in vitro	ISO 24443:2021 Cosmetics — Determination of sunscreen UVA photoprotection in vitro
	ISO 16217:2020 Water immersion procedure for the determination of water resistance
	New label instructions for the application of aerosol and pump pack sunscreens.
	New flow chart for determining requirements for secondary and primary sunscreens.

Table 9: Changes in ISO 24444:2010 compared to ISO 24444:2019 cosmetic - Sun protection test methods - in vivo determination of the SPF.

Topic	ISO 24444:2010	ISO 24444:2019
Definition of minimal erythema response (MED) criteria has been revised.	Lowest dose of ultraviolent radiation (UVR) that produces the first perceptible unambiguous erythema with define boarders appearing over most of the field of UV exposure, 16h to 24 h after UV exposure	Lowest erythemal effective radiant exposure (Her) that produces the first perceptible unambiguous erythema with define boarders appearing over more than 50% of UV exposure subsite, 16h to 24 h after UV exposure
Selection of test subject	Test subjects included in the SPF test shall be only phototypes I, II or III according to Fitzpatrick or shall have an ITA° value > 28° by colorimetric methods	Test subject shall have ITA° at least 28° by colorimetric method. Colorimetric ITA values and skin colour categories are defined by the colorimetric descriptors of Chardon using CIE lab colour space (Annex A) (Fitzpatrick skin type selection not included)
Source of ultraviolent radiation Apparatus and material	The intensity of the beam shall be as uniform as possible. The minimum beam irradiance, at any sub-site, shall be no more than 10 % lower than the maximum beam irradiance at any sub-site.	Includes more detailed information and limits. Uniformity of beam shall be measured depending on the solar simulator type using either UV sensitive film or UV sensor method. UV film densitometry: Exposure dose of the UV sensitive film shall be calibrated to achieve film darkening to a density in the mid-range of the scale. Uniformity shall be >90%. UV Radiometer method: UV radiometer sensor used to sample the beam intensity at multiple sites. Multiple output device. New test methods are provided to determine the uniformity of the beam of both large and small beam size solar stimulator. A requirement for uniformity greater than or equal to 90% has been added.

Topic	ISO 24444:2010	ISO 24444:2019
Total Irradiance	Total irradiance shall not exceed 1 600 W/m2. The calibrated criteria for the solar simulator not included.	Total irradiance shall not exceed 1 600 W/m2. The output of the solar simulator shall be measured with broad spectrum sensor (capable of measuring between 280-1600nm) calibrated against the standard reference.
The test subject is based on the individual typology angle (ITA°)	Value characterizing the skin colour of the subject.	Value characterizing the skin colour of the subject as measured by skin contact reflectance spectrophotometer or skin colourimeter. The test subject is based on the individual typology angle (ITA°) with the average of test panel to be within the range 41°-55° with minimum of three subjects with in two of the three ITA° ranges.
		The ITA° is used to define the range of unprotected MED doses for the provisional or the test day unprotected MED determination.
Reference standard sunscreens added to validate SPF test panels	P2, P3, P7. Expected SPF<SPF20 any of the P2, P3 or P7 reference standard can be used. Expected SPF> SPF 20 one of the P2 or P3 standard is used.	Three new reference standard sunscreens (P5, P6 and P8) are added to validate SPF test panels for products with SPF equal to 25 or higher. SPF claim <24: P2 or P3 SPF> 25 but less than SPF 50: P5 of P6 (on at least 5 subjects) and P2 or P3 on remaining subjects. SPF>50: P8 (on at least 5 subjects) and P2 or P3 on the remaining subjects.
		Sunscreen application procedure has been described in greater detail.
Addition of Annex	Not present	An informative Annex F is added with photographic examples of erythema responses with guidelines for grading.
	Not present	The reporting table in Annex G and requirement in Clause 11 have modified to provide more complete information on the results of the testing.
		Bibliography updated.

Table 10: Changes in ISO 24443:2021 Determination of sunscreen UVA photoprotection in vitro compared to ISO 24443:2012

Changes in ISO 24443:2021 compared to ISO 24443:2012
Acceptance of module and introduction of sandblasted PMMA (polymethylmethacrylate) plates, according to specifications described in Annex D.
Product application fitted to 1,2 mg/cm2 for sand blasted plates.
Description of application gesture according to tested products.
Introduction of a new high UVA PF standard P8 in addition to S2 in the ISO-24443-2012.
Introduction of critical length calculation.
Calculation of coefficient ‘C’ accepted from in vivo screening SPF, with specific conditions based on SEM and percentage of variability and new range proposed from 0,6 to 1,6.
Pre-Irradiation dose should be limited at a maximum of 36J/cm2 (UVA-PF0 maximum 30).

Changes in ISO 24443:2021 compared to ISO 24443:2012
Additional capabilities – Sandblasted PMMA plates P8 reference standard.
The acceptable time for water immersion is 4hrs as described in the AS/NZS 2604 update.

Table 11: ISO 16217: 2020 Water immersion procedure for the determination of water resistance

Changes to ISO 16217: 2020
The process used is mostly described in ISO 24444. Australia retains the 4hr water test period and claim and, continue to determine SPF after immersion as the SPF value to use for labelling SPFs

Appendix 2: Excerpt from the Therapeutic Goods (Excluded Goods) Determination

Table 12: Schedule 1 – Specified goods

Item	Specified goods
14	products intended for application to the lips, that contain sunscreen, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iii) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012; and (iv) the product must meet the performance requirements for a ***broad-spectrum product*** set out in clause 6.3 of AS/NZS 2604: 2012 and Table 1 in clause 5.2 of AS/NZS 2604: 2012
15	tinted bases and foundations, such as liquids, pastes or powders, that contain sunscreen, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iii) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012; and (iv) the product must meet the performance requirements for a ***broad-spectrum product*** set out in clause 6.3 of AS/NZS 2604: 2012 and Table 1 in clause 5.2 of AS/NZS 2604: 2012

Item	Specified goods

Table 13: Schedule 2 – Specified goods used, advertised or presented for supply in a particular way

Item	Specified goods	When used, advertised or presented for supply in a particular way
5	moisturising skin care products, that contain sunscreen, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, for dermal application, including anti-wrinkle, anti-ageing and skin whitening products, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:2012; and (ii) the product meets the performance requirements for a ***broad-spectrum product*** set out in clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012; and (iii) any protection factor or equivalent category	when the product: (a) is not advertised or presented for supply as having a sun protection factor of more than 15; and (b) is not advertised or presented for supply as being water-resistant; and (c) if the product is not stable for at least 36 months – includes an expiry date on its label; and (d) has a pack size not larger than 300mL or 300g; and (e) except in the manner provided below, does not have any therapeutic claims made in relation to it, including claims about skin cancer; and therapeutic claims made in relation to the product are limited to those in relation to premature ageing in connection with sun exposure, and are only made if the product meets the performance requirements for ***broad-spectrum product*** set out in: (a) clause 7.2 of AS/NZS 2604:1998; or (b) both clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012

Item	Specified goods	When used, advertised or presented for supply in a particular way
	description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iv) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012	
9	preparations containing a sunscreening substance, if the primary purpose of the preparation is neither protection from solar radiation nor another therapeutic purpose	when the preparation is not advertised or presented for supply with: (a) a statement of claimed sun protection factor; or (b) a description of a claimed sun protection factor; or (c) a reference to another therapeutic use in respect of the preparation
10	sunbathing skin care products, such as oils, creams, gels, tanning products without sun and after-sun care products, that contain sunscreen with a sun protection factor of at least 4 and not more than 15, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or	when the product: (a) is not advertised or presented for supply as having a sun protection factor of more than 15; and (b) is not advertised or presented for supply as being water-resistant; and (c) if the product is not stable for at least 36 months – includes an expiry date on its label; (d) has a pack size not larger than 300mL or 300g; and (e) except in the manner provided below, does not have any therapeutic claims made in relation to it, including claims about skin cancer; and therapeutic claims made in relation to the product are limited to those in relation to premature ageing in connection with sun exposure, and are only made if the product meets the performance requirements for ***broad-spectrum product*** set out in: (a) clause 7.2 of AS/NZS 2604:1998; or (b) both clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012

Item	Specified goods	When used, advertised or presented for supply in a particular way
	after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:2012; and (ii) the product meets the performance requirements for a ***broad-spectrum product*** set out in clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012; and (iii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iv) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012	

Appendix 3: Regulatory costings for industry

A Regulatory Burden Measurement Framework has been applied to each option outlined in this Impact Analysis, and follows the guidelines provided by the Office of Impact Analysis[52]. As per the guidelines of the Office of Impact Analysis, costs are presented on an average per year basis and the regulatory burden measurements are calculated on a ten-year basis, which incorporates the proposed transition periods provided in Options 2 and 3.

Methodology for determining regulatory cost

Determination of number of products in the ARTG

A list of sunscreens listed in the ARTG (that are assigned a product code of "DCS") was extracted from an internal TGA system on 6 October 2023. There was a total of 917 products and a breakdown of their dosage forms is provided below in table 13.

Table 14: Breakdown of sunscreen dosage forms

Dosage form	Number of products
NON-AEROSOLS	
Application	3
Cream	292
Gel	8
Liquids	1
Lotion	422
Ointment	3
Stick	99
Stick, lip	11
Total	**839**
AEROSOLS	
Spray	66
Spray, pressurised	11
Spray, solution	1
Total	**78**
Grand total	**917**

Limitations to determining number of products in the ARTG

'Aerosols' is not listed as a dosage form, as such, the following dosage forms were used to represent aerosols and spray pump packs:

- 'spray'
- 'spray, pressurised'
- 'spray, solution'

Regulatory burden calculations

Data was sought from industry to determine the costs of adopting the 2021 Sunscreen Standard.

In addition, sunscreen testing laboratories were contacted to provide the costings for testing to the requirements outlined in the 2021 Sunscreen Standard.

Limitations to determining the regulatory burden calculations

The following limitations are noted with the data collected:

[52] https://oia.pmc.gov.au/resources/guidance-assessing-impacts/regulatory-burden-measurement-framework

- Organisations have different approaches and methods when formulating products, as such, the data and costs were not provided in a consistent manner to enable consistent calculations.
- There were gaps in the data provided by industry, including but not limited to: inadvertently missed costs; costs unable to quantified; and some costs were provided aggregated into groups rather than a breakdown per steps in the manufacturing process (i.e. stability assessment vs SPF testing).
- The spread of the data was broad which affected the average that was calculated.

Assumptions

- The subset of industry sponsors that data was collected from were considered to be representative of all sponsors and manufacturers, as and therefore, was used to project the costing for all 917 products listed in the ARTG.
- The regulatory burden that has been calculated is the maximum cost (i.e. worst case scenario) to industry if all 917 products require reformulating and are tested to SPF of 50 or greater.
- However, the costing does not include instances where there are reformulation failures, i.e. where reformulating and re-testing is required, rather, the costing is based on the scenario that the requirements are met at the first attempt.
- The actual costs should be significantly lower due to:
  - there are lower costs associated with testing SPF below 50
  - not every product will require reformulation
  - some products will already (or soon will be) compliant with aerosol labelling and/or testing requirements of the 2021 Sunscreen Standard, therefore there will be no additional costs
  - sponsors may voluntarily de-list their products from the ARTG
  - due to the normal life cycle of products, there may already be planned changes to labelling, promotional or advertising material scheduled in, as such, adopting the 2021 Sunscreen Standard will pose no additional regulatory burden for writing off these materials
  - with the longer transition time, the less products with a short commercial life will require re-testing to the requirements of the 2021 Sunscreen Standard

Concessions made

- An average of the data provided was used where possible.
- If data was missing for a particular field(s), then these were not included when calculating the average costs (as this would skew the results).

Calculation of regulatory cost for industry

Data was provided to the TGA ‘in-confidence’ and the calculations below only indicates figures and omits details of the number of respondents, identity of respondents and breakdown of each of the associated costs.

a. Cost of **testing** to the requirements of the 2021 Sunscreen Standard

- The average cost of testing was calculated per product.
- This cost was applicable to both aerosols and non-aerosols.

b. Costing for aerosol sunscreens to meet the **labelling** and **reformulation** requirements of the 2021 Sunscreen Standard

- The average cost of writing-off printed packaging was calculated per product.
- The average cost of reformulating a single product was calculated.
- The total = (cost of testing + cost of reformulating + cost of writing-off labels) x 78.

c. Costing of write-off of materials and reformulation of non-aerosol sunscreens to meet the requirements of the 2021 Sunscreen Standard

- The average cost of reformulating a single product was calculated.
- The write-off of stock was calculated for both 3-year and 5-year transition costs.
- Total for Option 2 = (cost of testing + cost of reformulating + write-of stock for 3-year transition) X 839 products.
- Total for Option 3 = (cost of testing + cost of reformulating + write-of stock for 5-year transition) X 839 products.

Table 14 provides the estimated worst-case scenario for transitioning to the 2021 Sunscreen Standard and has been used as the data source for establishing the regulatory burden of Options 2 and 3.

Note that the costing relates to actual costs to test to the requirements of the 2021 Sunscreen Standard and not additional costs. Sunscreen testing facilities were unable to provide a direct cost comparison between the 2012 Sunscreen Standard and 2021 Sunscreen Standard due to a number of factors affecting pricing structure including, inflation and routine yearly price changes.

Table 15: Costs to comply with 2021 Sunscreen Standard per product

• **Costs of transition per product**		
Cost of 2021 Sunscreen Standard testing per product		
ISO 24444:2019		$5,287
ISO 24443:2021		$765
ISO 16217:2020		$8,250
TOTAL testing costs		**$14,302**
Other potential costs of transition per product		
Costs	Comment	Cost per product
Cost of reformulation	May be required to comply with new testing requirements	$64,500
Cost of new labels and/or promotional materials	May be required for aerosol sunscreen products that do not have label advisory statements.	$8,500
Costs of write-off of labels and product	May not be required if sponsors have enough transition period to manage their existing stock	$40,000
TOTAL other potential costs		**$113,000**

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Version	Description of change	Author	Effective date
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