

Consultation on a proposed exposure model for assessing the safety of sunscreen ingredients in Australia

Tell us what you think about Option 1: Australian Sunscreen Exposure Model (ASEM)

The ASEM calculates the highest estimated daily sunscreen exposure, by integrating expected sunscreen application practices with current evidence-based Australian recommendations and research, rather than relying on international models. This approach ensures that risk assessments, when based on individuals that use a high amount of sunscreen, also ensure safety for individuals that use less sunscreen.

Please refer to the consultation paper for more detail on Option 1.

1. Should the TGA implement Option 1, by using the highest estimated daily sunscreen exposure for Australians (i.e. 673 mg/kg bw/day and 336 cm²/kg bw/day) in ingredient risk assessments?

Yes

No

Please describe why/why not

While we are in principle supportive of Option 1, there remain areas to be addressed.

CTFAS acknowledges the intensive effort partaken by TGA to develop a holistically thought-out exposure model that takes into account Australian-specific exposure and habits/practices. If applied appropriately, the ASEAM has the potential to be a powerful and nuanced risk-based safety assessment tool.

One of the key oppositions to Option 1 is the application of a single exposure number of 673 mg/kg bw/day and 336 cm²/kg bw/day in ingredient risk assessments regardless of actual risk scenarios posed by specific ingredient/product type and use (e.g. primary or secondary sunscreen). This can be overly conservative and simplified and hence leads to potential issues for determining the MOS of UV actives, consequently undermining the intended effectiveness of ASEM data.

Not every sunscreen product is a whole-body primary sunscreen product. We know that secondary sunscreen products such as moisturisers with UV filters and primary sunscreen products specifically formulated and marketed as facial sunscreens are used by consumers in very different ways to whole-body primary sunscreen products. Generally speaking, consumers that use sunscreen products regularly use different products for different sun exposure scenarios e.g. use moisturiser with medium-high SPF protection (secondary sunscreen) before

morning commute to work and primary sunscreen with high SPF for outdoor activities like swimming or gardening.

The benefit of a proper risk assessment, one that does not over-simplify risk to the 'worst-case', is significant. A more nuanced risk assessment would allow a greater range of ingredients, both active and excipient ingredients, to be safely used in sunscreen products. This in turn allows more innovation in sunscreens, leading to better products and more consumer choice, which in turn leads to greater sunscreen use.

To improve public health protection from use of sunscreen products, we need regulation that allows the greatest 'palette' of sunscreen ingredients, without jeopardising safety. This will not be possibly achieved from Option 1 approach as it is presented, as it is overly conservative, too simplistic and does not consider the ranges of different product uses or differences in physicochemical properties across ingredients.

We therefore urge the TGA to rethink Option 1 to increase its flexibility, while continuing to maintain consistency by using the ASEM calculation process that is suitable for different sunscreen ingredients and use scenarios.

The TGA should also consider how the ASEM process will apply in the individual ingredient assessment process. While MoS of 100 is used as a 'pass score', it is well understood by toxicologists that it is not a safe/unsafe level marker and closer look at the risk is needed where the MoS is close to 100, whether above or below the number.

We look forward to further conversations with the TGA to understand how the ASEM will be used in individual ingredient considerations to consider the unique risk/benefits of each ingredient, for the best possible risk management outcome.

2. Do you agree with the calculations and assumptions for the ASEM formula, ASEM scenarios, and how the highest estimated daily sunscreen exposure has been derived?

Yes

No

3. Do you have any additional data, information or comments that may assist in refining Option 1?

We would also like to clarify how the two different calculation approaches will be used, if dermal absorption data is reported as both % and ug/cm². We assume

that passing either will be acceptable, however, clarity on this point would be appreciated.

Tell us what you think about Option 2: Scientific Committee on Consumer Safety (SCCS) sunscreen exposure model

This model is well-established and applied by some international regions such as Europe, where sunscreens are regulated as cosmetics. However, the estimated daily sunscreen exposure is derived from information and assumptions that may not reflect how sunscreen is used in Australia. The TGA seeks to ensure that any model adopted is reflective of Australian sunscreen use and provides a realistic and safe framework for evaluating sunscreen ingredients.

Please refer to the consultation paper for more detail on Option 2.

4. Should the TGA implement Option 2 by using the estimated daily sunscreen exposure described in the SCCS (i.e. 300 mg/kg bw/day and 583 cm²/kg bw/day) in ingredient risk assessments?

Yes

No

Please describe why / why not

CTFAS does not oppose the implementation of Option 2. We note that the SCCS model is a model that is used broadly, not only by industry but also by regulators in the EU and other economies that have modelled their cosmetics regulations on the EU Cosmetics Regulations, which include us in the ASEAN region.

Use of the SCCS model would align Australia's sunscreen ingredient risk considerations with the majority of overseas markets, and minimise situations where an ingredient that is available overseas cannot be made legally available in Australia, but Australian consumers can still access the products via retailers online.

That being said, we do acknowledge the concerns raised by the TGA and believed a right-sized risk-based approach, whether it's ASEM or SCCS, that provides realistically conservative risk management for the Australian sun exposure conditions will be the intended goal.

5. If you support Option 2, please explain how the SCCS model accounts for the Australian sunscreen use context, or how the model can be modified to better reflect Australian context.

N/A

Tell us what you think about Option 3: Status quo

This option involves not adopting a specific sunscreen exposure model and continuing to evaluate sunscreen ingredients on a case-by-case basis using various approaches.

Please refer to the consultation paper for more detail on Option 3.

6. Do you support Option 3?

Yes

No

Please describe why / why not

While maintaining flexibility is imperative to minimize regulatory burdens, we acknowledge that there are benefits in having a transparent, consistent and robust exposure model to better protect the interests/safety of Australian consumers, while balancing the efforts and implications imposed on industry.

Reiterating our earlier inputs, a right-sized risk-based approach, whether it's ASEM or SCCS, that provides realistically conservative risk management for the Australian sun exposure conditions will be the intended goal.

7. Which is your preferred option?

Option 1

Option 2

Option 3

8. Do you have an alternative option to propose?

N/A